CHAPTER 51

PHARMACEUTICAL SERVICES

TABLE OF CONTENTS

SUBCHAPTER 1. PHARMACEUTICAL SERVICES

10:51-1.1 Introduction

(a) This chapter provides information about the provision of pharmaceutical services under the New Jersey Medicaid program and NJ FamilyCare program. It is divided into three subchapters.

1. N.J.A.C. 10:51-1 provides a pharmacy operating under a retail permit with the policies and procedures relevant to the provision of services to New Jersey Medicaid and NJ FamilyCare fee-for-service beneficiaries, excluding those residing in a nursing facility.
2. N.J.A.C. 10:51-2 pertains to a pharmacy providing pharmaceutical services to Medicaid beneficiaries in a nursing facility.
3. N.J.A.C. 10:51-3 explains the responsibility of a pharmacist acting as a consultant in a nursing facility or other public medical institution.

(b) Incorporated by reference into this chapter as Appendix D is the Fiscal Agent Billing Supplement that provides information about claim processing and related activities.

10:51-1.2 Participation of eligible providers

(a) A pharmacy, with a retail or institutional permit, may participate in the Medicaid or NJ FamilyCare program as a provider of pharmaceutical services; as a medical supplier providing medical supplies and durable medical equipment; and/or as a provider of parenteral nutrition and/or intravenous therapy. The requirements for approval as a provider of these services are listed in (b) through (d) below.

(b) To be approved as a provider of pharmaceutical services, the pharmacy shall:

1. Operate under a valid retail and/or institutional permit issued by the Board of Pharmacy of the State of New Jersey or by the Board of Pharmacy of the state in which the pharmacy is located. A pharmacy operating under an out-of-state institutional permit may not participate as an approved provider in the New Jersey Medicaid or NJ FamilyCare program; and
2. File an application and sign an agreement with the Division of Medical Assistance and Health Services.

i. Upon sale or other change of ownership of an approved pharmacy, the agreement is automatically terminated. To execute a new agreement to participate in the New Jersey Medicaid and NJ FamilyCare programs, the new owner(s) shall apply to the Division of Medical Assistance and Health Services, Department of Human Services, by contacting the Provider Enrollment Unit (see N.J.A.C. 10:49--Administration Chapter, Enrollment Process) or the fiscal agent Provider Enrollment Unit (see Appendix D, Fiscal Agent Billing Supplement).

3. To enroll as a Medicaid and NJ FamilyCare provider of pharmaceutical services, a pharmacy shall contact the fiscal agent Provider Enrollment Unit (see Appendix D, Fiscal Agent Billing Supplement).

(c) A pharmacy may also participate as a medical supplier. The Medical Supplier chapter, N.J.A.C. 10:59, available from the fiscal agent, provides information concerning the provision of

and reimbursement for covered medical supplies and durable medical equipment provided by a medical supplier.

1. A pharmacy may apply to participate as a medical supplier by contacting the Provider Enrollment Unit (see N.J.A.C. 10:49--Administration Chapter, Enrollment Process) or the fiscal agent Provider Enrollment Unit (see Appendix D, Fiscal Agent Billing Supplement).

(d) Requirements for approval as a provider of parenteral nutrition and/or intravenous therapy are as follows:

1. In addition to the requirements for approval as a pharmacy provider listed under (b) above, a pharmacy who supplies parenteral nutrition and/or intravenous therapy shall:

i. Comply with all the requirements of N.J.A.C. 13:39; or

ii. Comply with similar applicable requirements of the state in which the applicant is located and submit a copy of the requirements of that state when applying for participation. A copy of N.J.A.C. 13:39 is available from West Group at 1-800-808-WEST.

2. Parenteral nutrition and/or intravenous therapy may be provided by either a pharmacy/medical supplier or a medical supplier approved to provide these services by the New Jersey Medicaid and NJ FamilyCare programs; however, billing for the ancillary supplies associated with parenteral nutrition and/or intravenous therapy are subject to the requirements of the Medical Supplier Chapter (N.J.A.C. 10:59).

i. "Ancillary supplies" means medical supplies and/or durable medical equipment which are medically necessary to facilitate administration of parenteral or intravenous therapy.

10:51-1.3 Conditions for participation as a provider of pharmaceutical services

(a) All participating pharmacies shall provide complete prescription services, including injectables and injectable anti-neoplastic agents, compounding, and prescription refill services, when allowable. Prescriptions must be dispensed in compliance with all current existing Federal and State laws.

(b) All drugs must be prescribed.

1. "Prescribed drugs" mean simple or compound substances or mixtures of substances prescribed for the cure, mitigation, or prevention of disease, or for health maintenance that are:

i. Prescribed by a practitioner licensed or authorized by the State of New Jersey, or the state in which he or she practices, to prescribe drugs and medicine within the scope of his or her license and practice;

ii. Dispensed by licensed pharmacists in accordance with regulations promulgated by the New Jersey State Board of Pharmacy, N.J.A.C. 13:39; and

iii. Dispensed by licensed pharmacists on the basis of a written prescription that is maintained in the pharmacist's records.

(c) Participating pharmacies shall permit properly identified representatives of the Division of Medical Assistance and Health Services to:

1. Inspect written prescriptions on file;
2. Audit records pertaining to covered persons;
3. Inspect private sector records, where deemed necessary to comply with the Federal

regulations to determine a pharmacy's usual and customary charge to the public;

i. Information pertaining to the patient's name, address, and prescriber will remain confidential within the limits of the law. Only the following items may be reviewed:

(1) Drug name;

(2) Quantity dispensed;

(3) Price;

(4) Prescription number (for reference purposes only); and

(5) Date dispensed;

ii. The pharmacy shall provide sufficient information with regard to its contractual agreement(s) and payment history with other private third party prescription plans to identify and verify number of claims, amount paid, and dispensing fee paid by group contracts within the plan. Records and contracts shall be available on-site at the time of audit; or available within 10 working days of an on-site audit. Records shall include, but not be limited to:

(1) Payment vouchers;

(2) Contracts; and

(3) Agreements; and

4. Inspect records of purchases of covered drugs for which claims have been made for reimbursement.

10:51-1.4 Program restrictions affecting payment for prescribed drugs

(a) The choice of prescribed drugs shall be at the discretion of the prescriber within the limits of applicable law. However, the prescriber's discretion is limited for certain drugs. Reimbursement may be denied if the requirements of the following rules are not met:

1. Covered and noncovered pharmaceutical services as listed in N.J.A.C. 10:51-1.11 and 1.13, respectively;

2. Pharmaceutical service requiring prior authorization (see N.J.A.C. 10:51-1.14);

3. Pharmaceutical services requiring pharmacist intervention as part of the Medicaid and NJ FamilyCare prospective drug utilization review (PDUR) program (see N.J.A.C. 10:51-1.26).

4. Quantity of medication (see N.J.A.C. 10:51-1.15);

5. Dosage and directions (see N.J.A.C. 10:51-1.16);

6. Telephone-rendered original prescriptions (see N.J.A.C. 10:51-1.17);

7. Changes or additions to the original prescription (see N.J.A.C. 10:51- 1.18);

8. Prescription refill (see N.J.A.C. 10:51-1.19);

9. Prescription Drug Price and Quality Stabilization Act (N.J.S.A. 24:6E-1 et seq.) (see N.J.A.C. 10:51-1.20);

i. Products listed in N.J.A.C. 8:71 (hereafter referred to as "the Formulary"), and all subsequent revisions, distributed to all prescribers and pharmacists; and

ii. Non-proprietary or generic dispensing (see N.J.A.C. 10:51-1.9).

10. Federal regulations (42 CFR 447.301, 331-334) that set the aggregate upper limits on payment for certain multi-source drugs if Federal Financial Participation (FFP) is to be made available. The limit applies to all "maximum allowable cost" drugs (see N.J.A.C. 10:51-1.5, Basis of payment);

11. Drug Efficacy Study Implementation (DESI): "Less than effective drugs" subject to a Notice

of Opportunity for Hearing (NOOH) by the Federal Food and Drug Administration (see N.J.A.C. 10:51-1.21 and listing of DESI drugs in Appendix A herein incorporated by reference);

12. Drug Manufacturers' Rebate Agreement with the Centers for Medicare and Medicaid Services (CMS) of the United States Department of Health and Human Services (see N.J.A.C. 10:51-1.22);

13. For claims with service dates on or after July 1, 1998, all drugs prescribed for the treatment of impotency shall be limited to male beneficiaries over the age of 18 years and to four treatments per month; and

14. For claims with service dates on or after August 1, 1998, prescribers must write "Diagnosis of Impotency" on the face of any prescription for impotency drugs. Claims for such prescriptions without this written statement shall be subject to recoupment by the State of New Jersey.

(b) If a prescription is not dispensed directly to the New Jersey Medicaid fee-for-service, NJ FamilyCare fee-for-service, or Work First New Jersey/General Assistance (WFNJ/GA) beneficiary for whom the prescription was written, and the claim charge exceeds $150.00, the individual picking up the prescription shall present the Medicaid Identification Card, the NJ FamilyCare Identification Card or the authorized documentation confirming WFNJ/GA eligibility of the beneficiary. Without the required proof of identity, the prescription shall only be dispensed in accordance with (b)1 and 2 below:

1. If the individual picking up the prescription cannot produce the beneficiary's eligibility documentation, then the non-beneficiary shall produce a valid driver's license as identification. Pharmacies shall record and maintain on file the driver's license number of the non-beneficiary picking up the prescription on the pharmacy signature log or a photocopy of the driver's license presented by the non-beneficiary. Payments for Medicaid fee-for-service or NJ FamilyCare fee-for-service covered pharmacy services not dispensed directly to the beneficiary for whom there is no documentation or a photocopy of the driver's license of the non-beneficiary picking up the prescription shall be subject to full recovery by the State.

2. This subsection shall not apply to prescription deliveries.

3. Such documentation shall be retained by the pharmacy for at least five years from the date the prescription was dispensed, and shall be available for review by the Division or its authorized representatives upon request.

10:51-1.5 Basis of payment

(a) This section provides a summary of the elements involved in the calculation of the payment of a legend or non-legend drug for both the Medicaid and NJ FamilyCare programs. The elements include the following:

1. Program restrictions affecting reimbursement for the dispensing of drugs as listed in N.J.A.C. 10:51-1.4;

2. Price information as supplied from a reference drug file contracted for this purpose by the fiscal agent and accepted by the Division as the primary source of pricing information for the New Jersey Medicaid Management Information System (NJMMIS). The drug price or ingredient cost shall not exceed the lower of the average wholesale price as supplied by the reference drug file contractor; the provider's usual and customary charge; or the drug's maximum allowable cost, if applicable (see (b) below);

i. The NJMMIS reference drug file is updated periodically by the fiscal agent based upon data supplied by First Data Bank (FDB). The update process provides the fiscal agent with current data to include changes in product description. Providers are made aware of therapeutic indications for various classes of drugs by product literature distributed by drug manufacturers and by various trade publications. Based on market information, providers can determine whether a product's therapeutic classification meet the criteria specified in N.J.A.C. 10:51-1.11 (Covered Pharmaceutical Services).

3. Federal regulations (42 CFR 447.301, 331-334) set the aggregate upper limits on payment for certain covered drugs in the Medicaid and NJ FamilyCare--Plan A pharmaceutical programs. The Division applies the limits to NJ FamilyCare--Plan B and C. The Division refers to these upper limits as the "maximum allowable cost" (see (b) below); and

4. The provider's usual and customary charge for legend or non-legend drugs (see (c) below), contraceptive diaphragms and legend or non-legend devices.

(b) Payment for legend drugs is based upon the maximum allowable cost. This means the lower of the upper payment limit price list (MAC price) as published by the Federal government or the average wholesale price (AWP). Appendix B is the listing of MAC drugs, and is hereby incorporated by reference.

1. Maximum allowable cost is defined as:

i. The MAC price for listed multi-source drugs published periodically by the Centers for Medicare and Medicaid Services (CMS) of the United States Department of Health and Human Services; or

ii. For legend drugs not included in (b)1i above, the Estimated Acquisition Cost (EAC), which is defined as the average wholesale price (AWP) listed for the package size (billed to the New Jersey Medicaid or NJ FamilyCare program), in current national price compendia or other appropriate sources (such as the First Data Bank (FDB) reference drug file contractor), and their supplements, minus regression category or discount.

2. For information about the "regression categories and discounts," see N.J.A.C. 10:51-1.6 and for usual and customary charge see N.J.A.C. 10:51-1.10.

3. If the published MAC price as defined in (b)1i above is higher than the maximum allowable cost which would be paid as defined in (b)1ii above, then (b)1ii above shall apply.

(c) The maximum charge to the New Jersey Medicaid or NJ FamilyCare program for drugs, including the charge for the cost of medication and the dispensing fee, shall not exceed the provider's usual and customary and/or posted or advertised charge.

(d) The maximum allowance for protein replacement supplements, specialized infant formulas and food oils under the New Jersey Medicaid and NJ FamilyCare programs is the lesser of:

1. The product's AWP plus 50 percent; or

2. The usual over-the-counter (OTC) retail price charged to the other persons in the community, whichever is less.

(e) For claims with service dates on or after July 15, 1996, the maximum allowance for non-legend drugs (including protein replacement supplements, specialized infant formulas and food

oils), devices, or supplies under the New Jersey Medicaid or NJ FamilyCare program shall be calculated in accordance with (b)1ii above.

1. The product AWP less a volume discount (see N.J.A.C. 10:51-1.6) plus dispensing fee (see N.J.A.C. 10:51-1.7); or

2. The usual over-the-counter (OTC) retail price charged to the other persons in the community.

(f) For claims with service dates on or after July 15, 1996, the maximum cost for each eligible prescription claim not covered by the Maximum Allowable Cost price, as defined in (b)1i above, shall be based on the Average Wholesale Price (AWP) of a drug, as defined in (b)1ii above, less a discount of 10 percent.

10:51-1.6 Discounts

For claims with service dates on or after July 15, 1996, the discount shall be 10 percent for each eligible prescription claim not covered by the Maximum allowable cost price.

10:51-1.7 Prescription dispensing fee

(a) The dispensing fee for legend drugs, dispensed by providers having retail permits to beneficiaries other than those in long-term care facilities, including State operated Intermediate Care Facilities/Mentally Retarded (ICFs/MR), nursing facilities and State and county operated long-term psychiatric hospitals, is $3.73. Additional dispensing fees (add-ons) per prescription shall be given to pharmacy providers who provide the following:

1. Twenty-Four Hour Emergency Service: $0.11. The provider shall have a 24-hour per day, 365-days-per-year prescription service available and shall have provided Medicaid or NJ FamilyCare beneficiaries opportunities to utilize this service.

2. Patient Consultation: $0.08. In addition to routinely monitoring beneficiary profiles for drug interactions, contraindications, allergies, etc., the provider shall, where appropriate, discuss the course of drug therapy with the beneficiary. This discussion must include emphasis on compliance with the prescriber's orders; proper drug utilization; cautions about possible side effects; foods to avoid; proper drug storage conditions; and any other information that will prove beneficial to the beneficiary while on drug therapy.

3. Impact Area Location: $0.15. The provider shall have a combined Medicaid/NJ FamilyCare, and Pharmaceutical Assistance to the Aged/Disabled (PAAD) prescription volume equal to or greater than 50 percent of the provider's total prescription volume.

i. The nursing facility prescription volume shall be included for the determination of total prescription volume in determining entitlement to the impact allowance.

(b) Providers of pharmaceutical services in assisted living residences (ALRs) and comprehensive personal care homes (CPCHs) shall be reimbursed a dispensing fee per prescription dispensed to residents of these facilities in accordance with (a) above.

(c) Price information is supplied from a reference drug file subcontracted for this purpose by

the fiscal agent and accepted by the Division as the primary source of pricing information for the New Jersey Medicaid Management Information System (NJMMIS). The calculated price shall not exceed the lower of the average wholesale price (AWP) or the Federal Fund Participation Upper Limit (FFPUL) as supplied by the reference drug file contractor.

(d) In order to receive any or all of the above increments, the provider shall certify annually to the Division on Form FD-70, that the service(s) as defined in (a) above, are being provided and/or that the provider is entitled to the impact increment as defined in (a) above.

1. Each claimed increment is subject to audit and retroactive recovery with appropriate penalties, if warranted, if the Division determines that the provider was not entitled to reimbursement for them.

(e) Failure to submit this report annually shall result in retail pharmacy provider payments based on the basic dispensing fee of $3.73.

10:51-1.8 Compounded prescriptions

(a) Compounded prescriptions may be reimbursed by the Medicaid and NJ FamilyCare programs. Compounded prescriptions are extemporaneously prepared mixtures of an active ingredient or ingredients and/or a pharmaceutical excipient or excipients and are dispensed by approved pharmacy providers.

1. Acceptable pharmaceutical excipients which do not contribute therapeutically to a compound, include, but are not limited to hydrophilic ointment, petrolatum, aquaphor, eucerin cream, phenol, menthol, resorcinol, caffeine, talc, simple syrup, aromatic elixir, distilled water, and glycerin.

(b) Claims for compounded prescriptions may be manually or electronically submitted to the fiscal agent through a point-of-sale (POS) claims adjudication system approved by the Division. (See N.J.A.C. 10:51-1.25).

1. A compounded prescription is indicated by the provider by the use of the "compound drug" indicator field on a manual claim or in a similar field in the EMC claim format.

(c) Reimbursement for compounded prescriptions shall not exceed the lower of:

1. The cumulative cost of the active ingredient(s), as described in N.J.A.C. 10:51-1.5, and/or pharmaceutical excipient(s), plus a dispensing fee, as described in N.J.A.C. 10:51-1.7; or

2. A provider's usual and customary charge.

(d) For compounded prescriptions without an active ingredient(s), reimbursement is based on the cumulative cost of the pharmaceutical excipient(s), unless otherwise specified by NCPDP standards, version 5.1 and version 1.1 as amended and supplemented, incorporated herein by reference. The Council's address is 4201 North 24th Street, Suite 365, Phoenix, Arizona 85016.

1. For pharmaceutical excipients costing less than $0.25, the provider may charge Medicaid or NJ FamilyCare $0.25 for each ingredient.

2. Reimbursement for compounded prescriptions without an active ingredient(s) shall be provided under a common drug code assigned by DMAHS.

(e) Reimbursement for compounded prescriptions submitted manually or as an EMC claim is calculated based on the ingredient cost, as described in N.J.A.C. 10:51-1.5, of the most costly active ingredient, plus a dispensing fee, as described in N.J.A.C. 10:51-1.7.

1. For compounded prescriptions without an active ingredient(s), reimbursement is based on (d) above, plus a dispensing fee, as described in N.J.A.C. 10:51-1.7.

(f) The maximum charge for a compounded prescription must not exceed the limits set forth in N.J.A.C. 10:51-1.15.

(g) Restriction in payments for compounded prescriptions are as follows:

1. All legend and nonlegend (OTC) ingredients which are contained in compounded prescriptions must be covered by a manufacturer rebate agreement (see N.J.A.C. 10:51-1.22). If the labeler code of any single ingredient is not manufactured by an approved manufacturer, the compounded prescription is not covered. Chemical ingredients without NDC codes are excluded.

2. All non-legend ingredients which are contained in compounded prescriptions must be covered by the Medicaid and NJ FamilyCare program. If a non-legend drug is not listed as covered in N.J.A.C. 10:51-1.11, the compounded prescription is not covered.

3. All legend ingredients which are contained in compounded prescriptions must be covered by the Medicaid or NJ FamilyCare fee-for-service programs. If a legend drug is a DESI (Drug Efficacy Study Implementation, see N.J.A.C. 10:51-1.21) drug, the compounded prescription is not covered.

4. Compounded prescriptions containing drugs not eligible for reimbursement under N.J.A.C. 10:51-1.13 are not covered.

10:51-1.9 Non-proprietary or generic dispensing

When medication is prescribed by its non-proprietary or generic name, the pharmacist shall dispense the least expensive, therapeutically effective equivalent product available, preferably one listed in the DURC Formulary. The labeler code and drug product code of the actual product dispensed must be reported on the claim form. The package size code reported may differ from the stock package size used to fill the prescription.

10:51-1.10 Provider's usual and customary charge or advertised charge

(a) The provider's usual and customary charge or advertised charge is an element considered in the calculation of the basis of payment for legend drugs (see N.J.A.C. 10:51-1.5, Basis of payment).

(b) The usual and customary charge to the Medicaid or NJ FamilyCare program is defined as the amount a provider charges the general public for a prescription for the same drug product (same NDC number) in the same quantity as the prescription being dispensed to a Medicaid or NJ FamilyCare beneficiary. "Usual and customary charge" means the actual charge made to the majority (51 percent) of the total patient population served by the individual pharmacy.

1. The provider shall not charge the programs more than would be charged to a cash

customer when the general public, including private third party plans, accounts for more than 50 percent of a provider's total prescription volume.

i. In the event Medicaid, NJ FamilyCare and/or PAAD represent more than 50 percent of a provider's total prescription volume, then, for reimbursement purposes, the provider's usual and customary charge may be considered the amount the programs would reimburse for the same services.

10:51-1.11 Covered pharmaceutical services

(a) All covered pharmaceutical services shall be provided within the scope of the N.J.A.C. 10:49, Administration, and this chapter, and billed to the fiscal agent on the claim form or other approved billing method (see Appendix, Fiscal Agent Billing Supplement).

(b) Covered pharmaceutical services include:

1. Prescribed legend drugs (for their medically accepted indication) as defined in Section 1927(k)(6) of the Social Security Act. "Legend drugs" mean those drugs whose labels include the legend statement "Caution: Federal Law Prohibits Dispensing Without a Prescription."

2. In order for a brand name non-legend drug to be covered, the prescriber must document “Brand Medically Necessary” on the prescription. Otherwise, only the generic non-legend product is covered.

3. Non-legend drugs, as follows, for which Federal Financial Participation (FFP) is available:

i. Contraceptive devices and contraceptive supplies (such as diaphragms, jellies, foams and condoms);

ii. Over-the-counter, family planning supplies (such as pregnancy test kits);

iii. Pharmaceutical inhalation devices;

iv. Diabetic testing materials;

v. Insulin needles and/or syringes;

vi. Insulin; and

vii. Antacids.

4. In addition, coverage of non-legend drugs for beneficiaries under the age of 21 shall also include:

i. Analgesics, Salicylates;

ii. Analgesics/Antipyretics, Non-salicylate;

iii. Antidiarrheals;

iv. Anti-Emetics;

v. Antiflatulents;

vi. Antihistamines;

vii. Antipruritics;

viii. Antitussives, non-narcotic;

ix. Cathartics;

x. Cough and cold preparations;

xi. Decongestants

xii. Emetics;

xiii. Expectorants;

xiv. Hematinics;

xv. Iron replacement supplements;
xvi. Laxatives;
xvii. Lice treatment products;
xviii. Multiple vitamin preparations;
xix. Oral anti-inflammatory agents;
xx. Pediatric vitamin preparations;
xxi. Vitamins A, B, C, D, E, K, B1, B2, B6, B12 preparations;
xxii. Polymixin and derivatives;
xxiii. Topical preparations, antibacterial;
xxiv. Topical antibiotics; and
xxv. Topical anti-inflammatory preparations.

(c) For beneficiaries in the Medically Needy component of the New Jersey Care ... Special Medicaid programs, pharmaceutical services are available to pregnant women, dependent children and aged, blind or disabled Medically Needy beneficiaries residing in nursing facilities. For information on how to identify a Medicaid beneficiary, see N.J.A.C. 10:49, Administration.

(d) Prescribed legend drugs commercially available in unit-dose packaging, dispensed as part of a unit-dose drug distribution system, and/or unit-of-use packaging and dispensed to beneficiaries residing in nursing facilities (NFs), assisted living residences (ALRs) and comprehensive personal care homes (CPCHs) shall be a covered service under the following circumstances:

1. For unit-dose drug distribution systems, drugs shall be delivered to the resident's living area in single unit packaging which meets the following criteria:

i. Each resident shall have his or her own medication tray labeled with the resident's name and location in the facility;

ii. Each medication shall be individually wrapped and labeled by the manufacturer with the generic or trade (brand) name and strength of the drug, lot number or reference code, expiration date, dose, and manufacturer's name, and shall be ready for administration to the resident;

iii. Cautionary instructions shall appear on the resident's record of medication, and the system shall include provisions for noting additional information, including, but not limited to, special times or routes of administration and storage conditions; and

iv. Delivery and exchange of resident medication trays shall occur promptly, and at least one exchange of resident medication trays shall occur every 24 hours, including weekends and holidays.

2. For unit-of-use packaging, drugs shall be delivered to the resident's living area either in single unit packaging, bingo or punch cards, blister or strip packs, or other system where each drug is physically separate. Individually labeled unit-dose medications may be combined in a "bingo or punch card" to create a unit-of-use drug distribution system.

(e) For beneficiaries covered under a managed care contract, atypical antipsychotics shall be reimbursed fee-for-service through the State's fiscal agent.

(f) Anti-impotency drugs shall be covered, not to exceed four doses per month. Each

prescription shall include a diagnosis related to impotency.

10:51-1.12 Personal contribution to care requirements for NJ FamilyCare-Plan C and copayments for NJ FamilyCare-Plan D

(a) General policies regarding the collection of personal contribution to care for NJ FamilyCare-Plan C and copayments for NJ FamilyCare-Plan D are set forth at N.J.A.C. 10:49-9.

(b) Personal contribution to care for NJ FamilyCare-Plan C services are $1.00 per dispensing for generics and $5.00 per dispensing for brand name drugs. Included in drugs are insulin, needles and syringes.

(c) Pharmacies are required to collect the personal contribution to care for the above mentioned NJ FamilyCare-Plan C services if the NJ FamilyCare Identification Card indicates that a personal contribution to care is required and the beneficiary does not have a NJ FamilyCare form which indicates that the beneficiary has reached their cost share limit and no further personal contributions to care are required, until further notice. Personal contribution to care charges cannot be waived.

(d) The copayment for prescription drugs under NJ FamilyCare-Plan D shall be $5.00 per prescription:

1. If greater than a 34-day supply of a prescription drug is dispensed, a $10.00 copayment shall apply.

(e) Pharmacies shall collect the copayment specified in (d) above. Copayments shall not be waived.

10:51-1.13 Non-covered pharmaceutical services

(a) The following classes of prescription drugs or conditions are not covered under the New Jersey Medicaid or NJ FamilyCare fee-for-service programs. For beneficiaries in the Medically Needy component of the New Jersey Care . . . Special Medicaid Programs, pharmaceutical services are not available to the aged, blind nor the disabled who are residing in a long-term care facility (except a nursing facility) or in the community. For information on how to identify a covered person, see N.J.A.C. 10:49, Administration.

1. Prescriptions which are not for medically accepted indications as defined in Section 1927(k)(6) of the Social Security Act;
2. Antiobesics and anorexiants, with the exception of lipase inhibitors, when used in treatment of obesity (see N.J.A.C. 10:51-1.14, Prior authorization); coverage of lipase inhibitors shall be limited to obese individuals with a Body Mass Index (BMI) equal to or greater than 27 kg/m2 and less than 30 kg/m2 with co-morbidities of hypertension, diabetes or dyslipidemia; and obese individuals with a BMI equal to or greater than 30 kg/m2 without co-morbidities;
3. Drug products for which adequate and accurate information is not readily available, such as, but not limited to, product literature, package inserts and price catalogues;
4. Experimental drugs;

i. Exception: Drugs available only for treatment through an Investigational New Drug (IND) application shall be prior authorized;

5. Medication furnished by a prescriber or an employee of a prescriber;

6. Medication prescribed for hospital inpatients;

7. Non-legend drugs other than antacids; contraceptive devices and contraceptive supplies; diabetic testing materials; over-the-counter (OTC) family planning supplies; inhalation devices (pharmaceutical); insulin; and insulin needles and/or syringes;

i. Exception: Non-legend drugs described in N.J.A.C. 10:51-1.11, for beneficiaries under 21 years of age.

8. Prescriptions written and/or dispensed with nonspecific directions;

9. Food supplements, milk modifiers, infant formulas, therapeutic diets, special liquid or powdered diets used in the treatment of obesity;

i. Exception: Enteral nutritional products and electrolyte replacement supplements;

10. Methadone in any form (tablets, capsules, liquid, injectables, or powder) when used for drug detoxification or addiction maintenance (see N.J.A.C. 10:51-1.14, Prior authorization);

11. Drug products for which final orders have been published by the Food and Drug Administration, withdrawing the approval of their new drug application (NDA);

12. Drugs or drug products not approved by the Food and Drug Administration, when such approval is required by Federal law and/or regulation;

13. Radiopaque contrast materials (for example, Telepaque);

14. Drugs for which Federal Financial Participation (FFP) is not available, including:

i. Drug Efficacy Study Implementation (DESI) drugs and identical, similar and related drugs (see N.J.A.C. 10:51-1.21); and

ii. Drugs not covered by rebate agreements as defined in Section 4401 of OBRA '90 and Section 1927(a) of the Social Security Act (see N.J.A.C. 10:51-1.22);

15. Any bundled drug service (see N.J.A.C. 10:51-1.23);

16. Preventive vaccines, biologicals and therapeutic drugs distributed to hospital clinics and/or community health centers by the New Jersey Department of Health and Senior Services.

17. Drugs provided primarily for the treatment of infertility or which may be used to treat other conditions related to infertility, including fertility preparations and gonadotropic (follicle stimulating and luteinizing) hormones.

i. When a drug is provided that is ordinarily considered an infertility drug, but is provided for conditions unrelated to infertility, the claim must be sent with supporting documentation for medical review and approval of payment to the Division of Medical Assistance and Health Services, Office of Medical Affairs and Provider Relations, PO Box 712, (Mail Code #14), Trenton, New Jersey 08625-0712.

(b) Otherwise reimbursable products shall be excluded from payment, under the following condition(s):

1. Products whose costs are found to be in excess of defined costs outlined in N.J.A.C. 10:51-1.5, Basis of payment;

2. Drug products in dosage forms whose labeling, prescription or promotional material indicate the primary use is cosmetic in nature; for example, hair restoration;

3. Drug products available in unit-dose and/or unit-of-use packaging and dispensed to

residents in a boarding home, residential care setting, alternative family care (AFC) home or other community type setting. Other community type settings shall not include certain assisted living settings, including assisted living residences (ALRs) or comprehensive personal care homes (CPCHs) licensed by the Department of Health and Senior Services.

i. Drug products commercially available only as a unit-dose packaged product are covered in all settings when not otherwise marketed as a chemically equivalent product. The potency of the equivalent products may or may not equal the potency of the unit-dose-packaged product.

4. Prescriptions refilled too soon, as described in N.J.A.C. 10:51-1.19(a) 5; and

5. Drug products denied payment based on point-of-sale (POS) and prospective drug utilization review (PDUR) standards adopted by the Medicaid or NJ FamilyCare program. (see N.J.A.C. 10:51-1.26).

(c) Reimbursement shall not be made for any claim submitted by a provider which involves a beneficiary restricted to another pharmacy, except for an emergency situation (see N.J.A.C. 10:49, Administration).

10:51-1.14 Services requiring prior authorization

(a) The provider shall obtain prior authorization, when required by this chapter, by phone or in writing, from the professional staff of the Division's prior authorization agent for pharmacy services. The pharmacy prior authorization agent is available at a toll-free telephone number 24 hours a day, seven days a week. When a form is required by this chapter, the appropriate form that must be used to request prior authorization is indicated in the Fiscal Agent Billing Supplement. Information on the form is transmitted, on-line, from the pharmacy prior authorization agent to the fiscal agent who, in turn, confirms the status of the authorization request by mail and provides the specific prior authorization number. Additional requirements regarding prior authorization for specific drugs or classes of drugs are contained in (b) below.

1. In an administrative emergency (see N.J.A.C. 10:49-6.1(b)3) when the pharmacy prior authorization agent is unavailable, the provider may dispense a 72 hour supply of the prescribed drug.

i. If the drug is to be continued beyond 72 hours, and the pharmacy prior authorization agent is unavailable, the provider may dispense a total of a five day's supply. If the drug is to be continued either beyond the 72 hours or five days period, the provider shall hold the claim and obtain prior authorization for the balance of the prescription when the pharmacy prior authorization agent is available during normal business hours.

(b) The following drugs and specific therapeutic classes require prior authorization:

1. Enteral nutritional products and special infant formulas may only be authorized when medically necessary and when not available from the Women, Infants and Children (WIC) Nutritional program;

i. Medically necessary enteral nutritional products for treatment of beneficiaries, which may be administered orally, via naso-gastric tube, gastrostomy tube or needle catheter jejunostomy must be prior authorized. Special liquid or powdered diets for treatment of obesity or regular infant formulas are not considered enteral nutritional products;

ii. Electrolyte replacement supplements are not considered enteral nutritional supplements

and do not require prior authorization.

2. Methadone (not eligible for reimbursement when used for drug detoxification or for addiction maintenance);

3. Drugs available only for treatment through an Investigational New Drug (IND) application shall be prior authorized;

4. Anorexiants and antiobesics when used for treatment of conditions approved by the New Jersey State Board of Medical Examiners at N.J.A.C. 13:35-6.7;

5. Lipase inhibitors, used in the treatment of obesity, as follows:

i. The provider shall telephone the pharmacy prior authorization agent, using the toll-free telephone number supplied by the Division. Pharmacy prior authorization is available 24 hours a day, seven days a week. The pharmacy prior authorization agent reviews the information provided and automatically prior-authorizes a 30-day supply. Subsequent authorizations are based on criteria established by the New Jersey Drug Utilization Review Board, as specified in ii below.

ii. The lipase inhibitors will be provided for an initial 30-day period. A prior authorization will be issued without clinical criteria for an initial prescription for a maximum 30-day supply. During this initial 30-day period, the pharmacy prior authorization agent will contact the physician to request justification for continuing the use of the lipase inhibitor. If justification is received by the pharmacy prior authorization agent, the lipase inhibitor will be prior authorized for an additional 30-day supply. After these two 30-day periods, any subsequent provision of lipase inhibitors shall not be dispensed without prior authorization. Such subsequent prior authorizations for lipase inhibitors shall be limited to 90-day supply; and

6. Any prescription claim for the same beneficiary, provided within the same calendar month, that exceeds the monthly prescription volume threshold of 12 prescriptions per month. This applies whether the prescriptions were dispensed by one or more pharmacies. The need for prior authorization shall be communicated to providers via the point of sale claims processing system. Prior authorization shall be requested as required by (a) above, except that prior authorization shall not be required in the following circumstances:

i. Pharmaceutical services provided to Medicaid beneficiaries residing in a nursing facility, assisted living residence, comprehensive personal care home, or residential health care facility;

ii. Certain drugs and specific therapeutic drug classes including clozapine, antihemophiliac drugs, immunosuppressants, and HIV/AIDS drugs (limited to protease inhibitor, antiretroviral drugs, nucleoside analogs and reverse transcriptase inhibitors);

iii. Certain legend drugs, including oral contraceptives, ophthalmic preparations, otic preparations, nitroglycerin patches, vaginal preparations, and hemorrhoidal preparations;

iv. Drugs otherwise requiring prior authorization in accordance with this subsection;

v. Drugs otherwise requiring prior authorization by the Work First New Jersey/General Assistance program; and

vi. Drugs dispensed to beneficiaries in the pharmacy lock-in program.

10:51-1.15 Quantity of medication

(a) For claims with service dates on or after July 15, 1996, but prior to July 1, 1998, the quantity of medication prescribed shall provide a sufficient amount of medication necessary for the anticipated duration of the illness or, if required, an amount sufficient to provide medication

during intervals between prescriber visits. The amount of medication dispensed shall not exceed a 34-day supply or 100 unit doses, whichever is greater.

(b) For claims with service dates on or after July 1, 1998, but prior to July 1, 1999, the quantity of medication prescribed shall provide a sufficient amount of medication necessary for the anticipated duration of the illness or, if required, an amount sufficient to provide medication during intervals between prescriber visits. The amount of medication dispensed shall not exceed a 34-day supply.

(c) For claims with service dates on or after July 1, 1999, the quantity of medication prescribed shall provide a sufficient amount of medication necessary for the anticipated duration of the illness or, if required, an amount sufficient to provide medication during intervals between prescriber visits. The amount of medication dispensed shall not exceed a 34-day supply for initial prescriptions and a 34-day supply or 100 unit doses, whichever is greater, for refill prescriptions.

(d) Any medication continuously prescribed regardless of the frequency of administration, for a period of 14 days or more shall be considered a maintenance medication.

(e) The pharmacist shall dispense the full quantity of medication prescribed within the limitations described in (a) above.

(f) Prescriptions shall not be split or reduced in quantity, unless the quantity prescribed exceeds Program limits, in which case the quantity shall be reduced to Program limits described in (a) above.

1. Exception: When the full quantity prescribed (within Program limits) is not available when a prescription is ready to be dispensed, the pharmacist shall retain the claim form or submit an EMC claim after the balance of the medication is dispensed. The pharmacist may dispense the quantity available and shall notify the beneficiary accordingly.

10:51-1.16 Dosage and directions

(a) Dosage and directions for use shall be indicated on all prescriptions. Prescriptions written and dispensed with no specific directions, such as "prn," "as directed" or "ad lib," etc. are not eligible for reimbursement. Specific directions such as "1 tablet 4 times a day PRN" are required.

1. Exceptions:
   i. Topical preparations including ophthalmic and otic drops and ointments;
   ii. Aerosol inhalers; and
   iii. Nitroglycerin.
2. For all oral medication and injectables, the number of days the medication should last, based on the prescriber's directions of use, shall be entered in the "Days Supply" field on the pharmacy claim form or similar field in the EMC claim format.

(b) The number of days reported for the days supply dispensed on the pharmacy claim or in

the appropriate field on the EMC claim must accurately reflect the intended duration of drug utilization, or a reasonable estimation by the dispensing pharmacist of a drug's intended duration of use when a drug's dosage is unrelated to a specific days supply.

10:51-1.17 Telephone-rendered original prescriptions

(a) Telephone orders from prescribers for original prescriptions shall be permitted in accordance with all applicable Federal and State laws, rules and regulations.

(b) For purposes of reimbursement, telephone authorization to refill an original prescription with no refill remaining is considered a new order and requires a new written prescription with a new prescription number. Stamping or writing a new number on the original prescription order does not constitute a new prescription under the Medicaid or NJ FamilyCare programs.

(c) When a prescriber chooses not to allow product interchange on a telephone order, the statement "Substitution not permitted by prescriber-telephone Rx" plus the pharmacist's full signature next to or below the statement, shall appear on the prescription order. A rubber stamp bearing the statement is acceptable.

(d) When a prescriber chooses to certify "Brand Medically Necessary" on a telephoned prescription for a product included on the Federal MAC list, a written signed prescription order containing the certification, shall be sent to the pharmacist within seven days of the date of the telephone order. The written prescription shall be retained by the pharmacist as the original prescription. Failure to comply will result in the payment for that prescription being reduced to the MAC reimbursement level.

10:51-1.18 Changes or additions to the original prescription

Changes or additions to the original prescription, when approved by the prescriber, shall be clearly indicated (including date and time) and signed by the dispensing pharmacist. No changes (for example, dosage, quantity, number of refills, days supply, etc.) are permitted on the original prescription order after the claim is submitted for payment.

10:51-1.19 Prescription refill

(a) The provider shall submit a properly completed claim form or electronic claim in the proper EMC claim format to the fiscal agent for reimbursement of an allowable refill. An allowable refill shall comply with the following instructions in order to be reimbursed as such:

1. Refill instructions must be indicated in writing by the prescriber on the original prescription or verbally when telephoning the original prescription to the pharmacist. Verbal instructions shall be reduced to writing by the pharmacist, in accordance with N.J.S.A. 45:14-14.
2. When the prescriber indicates a prescription refill(s) on an original or telephone prescription for drugs, the number of refills shall be limited to a maximum of five refills within a six-month period.
3. Refill instructions indicating "refill prn" or indicating more than five refills, shall be subject to the limits imposed in (a)2 above, and shall be reimbursed up to these limits only.

4. A telephone authorized refill for a prescription with no refill remaining must be assigned a new prescription number.

5. Prescription refills shall not be dispensed until a reasonable quantity (approximately 75 percent) of the medication originally dispensed or refilled could have been consumed in accordance with the prescriber's written directions for use.

i. Exception: When a prescription is lost or destroyed, requiring a replacement prescription to be dispensed before the original prescription could have been consumed in accordance with the prescriber's written directions for use, an original pharmacy claim with written justification shall be submitted to the fiscal agent for payment consideration.

10:51-1.20 Prescription Drug Price and Quality Stabilization Act

(a) The Prescription Drug Price and Quality Stabilization Act, N.J.S.A. 24:6E-1 et seq., shall apply to the New Jersey Medicaid and NJ FamilyCare programs. This law requires that every prescription blank contain the statements "Substitution Permissible" and "Do Not Substitute." The prescriber shall initial one of the statements in addition to signing the prescription blank.

1. When the prescriber does not initial "Substitution Permissible" or the "Do Not Substitute" statement on a prescription for a drug product listed in the DURC Formulary, the pharmacist shall substitute from the list of interchangeable products and bill Medicaid or NJ FamilyCare accordingly.

2. When the prescriber initials "Substitution Permissible," the pharmacist shall dispense and bill Medicaid or NJ FamilyCare for one of the less expensive products listed in the DURC Formulary as interchangeable with the brand name prescribed. The Medicaid or NJ FamilyCare beneficiary must accept the interchangeable product unless the beneficiary is willing to pay the pharmacy's full, usual and customary price. If that occurs, the pharmacist shall so note on the prescription blank and no claim shall be submitted to Medicaid or NJ FamilyCare.

3. For non-MAC drugs (see N.J.A.C. 10:51-1.5) when the prescriber initials "Do Not Substitute," the pharmacist shall indicate the prescriber's preference by indicating "Medical Certification" on the claim form or the similar field in the EMC claim format and shall dispense and bill Medicaid or NJ FamilyCare for the prescribed product. Reimbursement will be the estimated acquisition cost (EAC) (see N.J.A.C. 10:51-1.5) plus applicable dispensing fee or the usual and customary charge, whichever is less for that product (see Appendix D, Fiscal Agent Billing Supplement for instructions about the claim form and Appendix E regarding the proper EMC claim format).

4. When the prescriber orders by the generic name, the DURC Formulary (see N.J.A.C. 10:51-1.4) does not apply. The pharmacist shall dispense the least expensive, therapeutically effective product available to him or her at the time of dispensing. The product need not necessarily be from the list of interchangeable products.

(b) Federal regulations prescribe the aggregate upper limit, for which Federal Financial Participation (FFP) is available, that Medicaid or NJ FamilyCare-Plan A may reimburse for certain multi-source drugs. The limit shall apply to all listed MAC drugs (see Appendix B) unless the prescriber indicates in his or her own handwriting on each written prescription or follow-up written prescription to a telephone rendered prescription (see N.J.A.C. 10:51-1.9) the phrase "Brand Medically Necessary." The Federal regulation requires a handwritten statement and

does not permit the use of alternatives such as a check-off box, initials or prescriber's signature, next to a preprinted statement "Do Not Substitute," nor does it allow a handwritten statement "Do No Substitute." For purposes of reimbursement, the physician's override capability under N.J.S.A. 24:6E-1 does not apply to drugs which have a Federal MAC limit. The Division shall also apply these Federal requirements to NJ FamilyCare- Plans B and C.

(c) Blanket authorization denying substitutions shall not be permitted. Each prescription order shall state "Brand Medically Necessary" in the prescriber's own handwriting. For non-MAC drugs, each prescription order shall follow the requirements of N.J.S.A. 24:6E-1 et seq. (see (a) above).

(d) For claims with service dates on or after July 1, 1999, the pharmacist shall dispense the least expensive, therapeutically effective nutritional supplement or specialized infant formula, at the time of dispensing, unless the prescriber indicates in his or her own handwriting on each written prescription or follow-up written prescription to a telephone rendered prescription the phrase "Brand Medically Necessary."

(e) The dispenser must always report the actual labeler code and drug product code of the drug dispensed. The package size code reported may differ from the stock package size used to fill the prescription.

(f) The "Brand Medically Necessary" requirement for MAC prescriptions shall not apply for Medicaid or NJ FamilyCare beneficiaries enrolled in a Medicaid or NJ FamilyCare participating Health Maintenance Organization (HMO).

10:51-1.21 Drug Efficacy Study Implementation (DESI)

(a) "Less than effective drugs" are subject to a Notice of Opportunity for Hearing (NOOH) by the Food and Drug Administration (FDA).

1. Reimbursement is not available for the purchase or administration of any drug product that meets all of the following conditions:

i. The drug product was approved by the Food and Drug Administration (FDA) before October 10, 1962;

ii. The drug product is available only through prescription;

iii. The drug product is the subject of a notice of opportunity for hearing issued under Section 505(e) of the Federal Food, Drug, and Cosmetic Act and published in the Federal Register on a proposed order of FDA to withdraw its approval for the drug product because it has determined that the product is less than effective for all its labeled indications; and

iv. The drug product is at present the subject of an efficacy review study performed by FDA (see 21 CFR 310.6 including all subsequent amendments and supplements). The FDA efficacy review potentially can determine justification for a drug product's medical need. If a drug product fails this review, the product is classified as a DESI drug.

2. Reimbursement is not available for the purchase or administration of any drug product that is identical, related or similar, as defined in 21 CFR 310.6 (including all subsequent amendments and supplements), to a drug product that meets the conditions of (a) above.

3. The initial identification of drugs and related drug products classified as "less than effective" by the FDA pending outcome of the NOOH appears at 21 CFR 310.6. Subsequent revisions to this list which are adopted, shall appear in the Federal Register.

10:51-1.22 Drug manufacturers' rebate agreement

(a) In order for legend drug products to be reimbursed by the New Jersey Medicaid or NJ FamilyCare program, manufacturers must have in effect a rebate agreement pursuant to Section 1927 et seq. of the Social Security Act (42 U.S.C. § 1396r-8(i)).

(b) Price information is supplied from a reference drug file subcontracted for this purpose by the fiscal agent and accepted by the Division as the primary source of pricing information for the New Jersey Medicaid Management Information System (NJMMIS). The calculated price shall not exceed the lower of the average wholesale price (AWP) or the Federal Fund Participation Upper Limit (FFPUL) as supplied by the reference drug file contractor.

10:51-1.23 Bundled drug service

(a) "Bundled drug service" means a drug or service that is marketed or distributed by the manufacturer or distributor as a combined package which includes in the cost the drug product and ancillary services such as, but not limited to, case management services and laboratory testing.

(b) Bundled drug service shall not be eligible for reimbursement by the New Jersey Medicaid or NJ FamilyCare program.

1. This provision may be waived at the discretion of the Commissioner if he or she determines that a bundled drug service is less than or equal to the total cost of the unbundled components if reimbursed separately; or

2. The Commissioner may waive the provisions for reasons of medical necessity for a bundled drug or in accordance with terms approved by the Department as follows:

i. Those instances where discontinuation, withdrawal, or elimination of the use of the bundled drug by someone who has been receiving a bundled drug would result in the deprivation of the life saving or life prolonging benefits of the drug or would cause potential harm or serious exacerbation of the illness being treated; or

ii. Those instances where use of the bundled drug has shown marked improvement in the beneficiary's clinical status reflected in alleviation of symptoms, and elevation of level of function and independence.

(c) In order to determine eligibility for reimbursement, manufacturers or distributors of a bundled drug service shall submit complete product information, including the cost to the programs of the total bundled drug service, discrete costs of each component of the bundled drug service, cost benefit analyses, and other information as requested by the Department, to the Chief Pharmaceutical Consultant, Division of Medical Assistance and Health Services, Mail Code #20, PO Box 712, Trenton, New Jersey 08625-0712.

1. If the Commissioner determines that a bundled drug is eligible for reimbursement under this section, New Jersey Medicaid or NJ FamilyCare beneficiaries shall receive or continue to

receive the bundled drug service if prior authorization is requested and approved. Prior authorization shall be obtained by completing the appropriate "Request for Authorization Form" requesting medication management authorization and providing sufficient documentation to establish that it is medically necessary to continue the bundled drug services. Mail all the information to:

Assistant Director
Office of Utilization Management
Division of Medical Assistance and Health Services
Mail Code #15
PO Box 712
Trenton, NJ 08625-0712

10:51-1.24 Claim submission

(a) An approved pharmacy provider may choose to:

1. Submit a properly completed hard copy pharmacy claim form approved by the New Jersey Division of Medical Assistance and Health Services (DMAHS).

2. Submit an electronic media claim (EMC) by modem, diskette or magnetic tape in an approved electronic format which complies with the National Council Prescription Drug Program (NCPDP) standards Version 5.1 and Version 1.1, as amended and supplemented, incorporated herein by reference. The Council's address is 4201 North 24th Street, Suite 365, Phoenix, Arizona 85016.

i. In order for a pharmacy provider to be eligible to submit an EMC claim to the Medicaid or NJ FamilyCare programs, a pharmacy provider or vendor of EMC services shall complete the "New Jersey Medicaid Provider Electronic Billing Agreement."

ii. The completed agreement shall be submitted to the fiscal agent and approved by the Division of Medical Assistance and Health Services.

iii. The pharmacy provider or vendor or EMC services shall submit electronic media claims under an approved submitter identification number and comply with EMC requirements contained in the EMC Manual, Appendix E, incorporated herein by reference.

iv. For the purposes of this subchapter, all electronically submitted claims, including POS claims, shall commonly be referred to as EMC claims; or

3. Enter into an agreement with a point-of-sale (POS) intermediary or directly provide a similar telecommunication network approved by DMAHS to submit claims to the fiscal agent for adjudication. POS claims require an electronic format approved by the Division which complies with the National Council Prescription Drug Program standards, Version 5.1 and Version 1.1, as amended and supplemented, incorporated herein by reference. The Council's address is 4201 North 24th Street, Suite 365, Phoenix, Arizona 85016.

i. The approved POS intermediary or provider established network shall enter into an agreement with the State of New Jersey to provider on-line telecommunication services, including transmission of pharmacy claim detail data, access to the fiscal agent's POS computer and return of adjudicated claim data to the provider.

(b) A properly completed claim form or a properly formatted electronic media claim (EMC) may be submitted to the fiscal agent, or transmitted by an approved POS intermediary or provider

established telecommunication network to the fiscal agent for claims adjudication.

1. A single claim form shall be completed manually or by computer or an EMC claim shall be transmitted in the approved EMC format for each Medicaid or NJ FamilyCare prescription dispensed. See Appendix D, Fiscal Agent Billing Supplement for instructions concerning the completion and submission of the specified claim form, and Appendix E regarding the proper EMC claim format.

2. All claim forms and EMC claims shall contain the National Drug Code (NDC) of the actual drug dispensed. The 11-digit NDC has three components. The first five digits are the manufacturer's labeler code, the next four digits are the product code, and the final two digits are the package size code. For claim submission, leading zeros shall be included in all fields. For example, 00003-0234-01.

i. The dispenser shall always report the actual labeler code and drug product code of the drug dispensed. The package size code reported may differ from the actual stock package size code reported on the claim.

3. All Medicaid or NJ FamilyCare fee-for-service pharmacy claims submitted to the fiscal agent for payment consideration shall be adjudicated based on the outcome of established POS and PDUR edits, regardless of the mode of claim submission.

10:51-1.25 Point-of-sale (POS) claims adjudication system

(a) Medicaid or NJ FamilyCare fee-for-service pharmacy claims may be submitted through a POS system and adjudicated by the State's fiscal agent on-line and in real time. The POS system is an alternative to other methods of claim submission, including magnetic tape, diskette and paper claims. The pharmacist would be required to enter pharmacy claim detail data into a computer or POS device and transmit this data to the fiscal agent over a dedicated telephone line. Regardless of the method of claim submission, all claims will go through all New Jersey Medicaid Management Information System (NJMMIS) claims processing edits and the claims will be processed to determine their payment disposition (for example, paid or denied).

(b) In order for a Medicaid or NJ FamilyCare approved pharmacy provider, in accordance with N.J.A.C. 10:51-1.3, to submit pharmacy claims through a POS system, the provider shall enter into an agreement with a POS intermediary or shall directly provide a similar telecommunications network approved by the New Jersey Division of Medical Assistance and Health Services.

1. In order to become an approved POS intermediary or provider established network, a firm shall notify the Division at the following address:

Division of Medical Assistance and Health Services
Office of Information Systems
Mail Code #4
PO Box 712
Trenton, New Jersey 08625-0712
Telephone: (609) 588-2802

2. The Division shall send the interested party a summary of the program and instructions on

how to submit an application.

3. The Division shall consider the following in evaluating an application:

i. The applicant's general approach and plans to meet the requirements of the POS project;

ii. The applicant's detailed approach and plans to meet the requirements of the POS project;

iii. The applicant's documented qualifications, expertise, and experience on similar projects;

iv. The applicant's proposed staff's documented qualifications, expertise, and experience on similar projects; and

v. The applicant's adherence to the requirements of the Centers for Medicare and Medicaid Services.

(c) A POS-participating pharmacy or intermediary shall supply the computer hardware or POS device and required software to generate electronic media claims (EMC) in a format consistent with POS standards adopted by the Division.

(d) A POS participating pharmacy or intermediary shall supply modem capability required to properly transmit claim detail data to the approved POS intermediary or to participate in the provider established telecommunication network.

(e) All Medicaid and NJ FamilyCare pharmacy providers choosing to submit claims through the POS system, shall submit claims in the approved electronic format, and transmit these claims on-line for adjudication by the fiscal agent's POS computer system.

1. Pharmacy services provided to nursing facility and residential care residents utilizing 24 hour unit-dose or modified unit-dose drug delivery systems are precluded from the POS system.

(f) Claim data requirements for electronic media claims (EMC) generated by POS participating pharmacies include:

1. The first five alpha characters of the last name and the first three alpha characters of the Medicaid or NJ FamilyCare beneficiary's first name;
2. The 12-digit Medicaid or NJ FamilyCare identification number;
3. The date of birth, if applicable;
4. The date of service or dispense date;
5. The pharmacy prescription number;
6. The actual 11 digit National Drug Code (NDC) of the drug dispensed;
7. The metric quantity dispensed;
8. The days supply;
9. The prescriber's Medicaid or NJ FamilyCare provider service number;
10. The third party payment, if applicable;
11. The provider's usual and customary charge; and
12. The pharmacy provider number.

(g) Additional supplementary data requirements, which are claim specific, shall include:

1. The medical certification indicator;
2. The nursing facility residency indicator;
3. The Medicaid, NJ FamilyCare or WFNJ/GA prior authorization number, if applicable;

4. The compound drug indicator;
5. The other insurance indicator, if applicable; and
6. The carrier code(s), if applicable.

(h) A POS-participating pharmacy or intermediary shall be required to implement software changes requested by the Division within 60 days of notification of such a request to ensure the generation of electronic claims acceptable to the Division.

(i) Pharmacy software must have the capability to display on-line adjudicated claim data returned to the pharmacy by the fiscal agent, including:
1. Payment disposition;
2. Error code message; and
3. Claim pricing data, including drug cost reimbursement, dispensing fee and applicable copayment amounts.

(j) Pharmacy software must provide the pharmacy with the capability of claim reversal and resubmission, if required.
1. A pharmacy may initiate a claim reversal of a previously submitted pharmacy claim for a period of 12 months from the initial date of claim service.
2. Pharmacies are required to initiate claim reversals for those services in which a claim was generated and adjudicated to payment by the fiscal agent's POS computer and the service was not subsequently provided to a Medicaid or NJ FamilyCare fee-for-service beneficiary.
3. All prescriptions adjudicated to payment by the fiscal agent's computer shall be subsequently dispensed and their receipt by Medicaid or NJ FamilyCare fee-for-service beneficiaries properly documented on a Medicaid/NJ FamilyCare-approved certification statement/signature log. (see N.J.A.C. 10:49-9.6).

(k) Pharmacies are required to interact with prescribers and/or beneficiaries at POS to resolve matters related to on-line messages resulting from claim adjudication by the fiscal agent.

(l) The following shall apply for coverage of prescriptions when provided to Medicaid/NJ FamilyCare or Work First New Jersey/General Assistance (WFNJ/GA) beneficiaries during an interruption in POS service:
1. Pharmacists shall confirm Medicaid/NJ FamilyCare eligibility by reviewing the respective eligibility card/letter, or by contacting the Recipient Eligibility Verification System (REVS) at 1-800-676-6562. If eligibility cannot be confirmed, pharmacists should follow the "good faith" guidelines as described in N.J.A.C. 10:49-2.10.
2. All claims for original prescriptions shall be payable for up to a 34-day supply initially. Upon refill, a 34-day supply or 100 dosage units, whichever is greater, shall be payable, if authorized by a prescriber.
3. Prior authorization (PA) requirements shall not apply to pharmacy services provided during a sustained interruption in POS service, except that prior authorization shall be required for those drugs identified by the New Jersey Drug Utilization Review Board as causing severe drug-drug interactions, if the interacting drugs are dispensed by the same pharmacy.

4. Pharmacies shall be responsible for, and shall not be reimbursed for, early refills and duplicate prescriptions dispensed by their own pharmacy. In the event that early refills or duplicate prescriptions submitted by the same pharmacy during a sustained interruption are paid, the Division of Medical Assistance and Health Services will institute recovery procedures subsequent to the restoration of service.

i. "Sustained interruption" means the period of time that POS service has been interrupted during which the Division of Medical Assistance and Health Services has notified pharmacies by fax and/or email of a sustained interruption in the POS system.

ii. "Brief interruption" means the period of time that POS service has been interrupted during which the Division of Medical Assistance and Health Services has not notified the pharmacies that the interruption is sustained.

5. The Division of Medical Assistance and Health Services will reimburse pharmacies for early prescription refills and duplicate prescriptions provided by another pharmacy during a sustained interruption in POS service.

6. After POS service is restored, pharmacies should submit claims which could not be processed during the interruption in POS service during off-peak hours. This will allow all pharmacies to receive timely responses to routine claims submitted immediately after service has been restored.

10:51-1.26 Prospective drug utilization review (PDUR) program

(a) The Division of Medical Assistance and Health Services has established a prospective drug utilization review (PDUR) program to assist pharmacy providers with monitoring drug utilization by Medicaid and NJ FamilyCare fee-for-service beneficiaries. As a component of the Medicaid/NJ FamilyCare point-of-sale (POS) claims adjudication system, the State's fiscal agent will review drug utilization based on claims submitted on-line and provide pharmacists with responses in real-time regarding utilization within PDUR standards recommended by the New Jersey Drug Utilization Review (DUR) Board, and approved by the Commissioner of the Department of Human Services (DHS) and the Commissioner of the Department of Health and Senior Services (DHSS). Similar responses related to EMC or paper claims processed by the New Jersey Medicaid Management Information System (NJMMIS) shall be received by pharmacies on the Remittance Advice statement.

1. PDUR standards recommended by the New Jersey DUR Board and approved by the Commissioners of the DHS and DHSS shall be based on standards in official compendia and accepted medical literature as included in those established by First Data Bank (FDB) as part of the FDB DUR information system. The FDB standards are incorporated herein by reference and may be obtained from First Data Bank, The Hearst Corp., 1111 Bayhill Dr., San Bruno, CA 94066.

2. PDUR standards recommended by the New Jersey Drug Utilization Review (DUR) Board and approved by the Commissioners of DHS and DHSS shall be applied to all pharmacy claims, regardless of mode of claim submission.

(b) POS participating pharmacy providers shall be required to meet the conditions described in N.J.A.C. 10:51-1.25.

(c) In addition to POS responses related to adjudication of Medicaid or NJ FamilyCare fee-for-service pharmacy claims returned to the pharmacy, pharmacists shall be notified regarding drug utilization inconsistent with adopted PDUR standards which may include, but not be limited to:

1. Drug-drug interactions;
2. Maximum/minimum daily dosage alerts;
3. Therapeutic duplication;
4. Drug age conflicts;
5. Duration of therapy;
6. Drug-pregnancy precautions.
7. Drug-gender conflicts;
8. Under-usage; and
9. Weight-based.

(d) The PDUR program may apply adopted standards based on a severity index recommended by the New Jersey DUR Board to determine appropriate pharmacist intervention and/or claim disposition (that is, payment or denial) of Medicaid and NJ FamilyCare fee-for-service pharmacy claims. (See N.J.A.C. 10:51-1.27)

(e) Based on the severity of a potential PDUR conflict or interaction, pharmacists shall be required to consult with the beneficiary and/or prescriber to resolve matters indicated by PDUR messages returned by the POS system.

(f) The pharmacists intervention requirements related to the PDUR program are in addition to beneficiary interactions related to the "offer to consult" as described in N.J.A.C. 13:39-7.14, Patient profile record system.

10:51-1.27 Medical exception process (MEP)

(a) For pharmacy claims with service dates on or after September 1, 1999, which exceed PDUR standards recommended by the New Jersey DUR Board and approved by the Commissioners of DHS and DHSS, the Division of Medical Assistance and Health Services has established a medical exception process (MEP) for Medicaid and NJ FamilyCare fee-for-service pharmaceutical services.

(b) The medical exception process shall be administered by a contractor, referred to as the MEP contractor, under contract with the Department of Human Services (DHS).

(c) The medical exception process shall apply to all pharmacy claims, regardless of claim media, unless exempted by the New Jersey DUR Board and the Commissioners of DHS and DHSS in accordance with the rules of those Departments.

(d) The medical exception process is as follows:

1. Pharmacy providers shall be notified when submitting a claim that a prescription is limited to a maximum 30-day supply.
2. The pharmacy shall be responsible to contact the MEP contractor to decide if a medical

exception is needed. If an exception is needed, the pharmacist may dispense medication for up to a 30-day calendar period. During this period, the MEP contractor shall issue a Prescriber Notification Letter which may include, but is not limited to, requesting from the prescriber the reason for the medical exception, diagnosis, expected duration of therapy, and the expiration date for the medical exception.

3. Following review and approval, if appropriate, of a prescriber's written justification, the MEP contractor shall override existing PDUR edits through the issuance of a prior authorization number.

4. The MEP contractor shall notify the pharmacy and prescriber of the results of the review by the close of the 30-day calendar period, and shall include, at a minimum, the beneficiary's name, mailing address, HSP number, the reviewer, service description, service date, and prior authorization number, if approved, the length of the approval and the appeals process if the pharmacist does not agree with the results of the review.

5. Pharmacies may request a fair hearing to appeal decisions rendered by the MEP contractor concerning denied claims (see N.J.A.C. 10:49-10, Notices, Appeals and Fair Hearings.)

6. Claims subject to the medical exception process which have exhausted the 30-day allowance period and for which prior authorization has not been issued by the MEP contractor shall be denied payment by the Medicaid/NJ FamilyCare programs.

END OF SUBCHAPTER 1

SUBCHAPTER 2. PHARMACEUTICAL SERVICES TO MEDICAID OR NJ FAMILYCARE FEE-FOR-SERVICES BENEFICIARIES IN A NURSING FACILITY

10:51-2.1 Introduction

This subchapter provides information about the provision of reimbursable pharmaceutical services provided to Medicaid or NJ FamilyCare fee-for-service beneficiaries in Medicaid approved nursing facilities.

10:51-2.2 Participation of eligible providers

(a) A pharmacy, with a retail or institutional permit, may participate in the Medicaid and NJ FamilyCare programs as a provider of pharmaceutical services, and as a provider of parenteral nutrition or intravenous therapy. The requirements for approval as a provider of pharmaceutical services are listed in (b) and (c) below.

(b) To be approved as a provider of pharmaceutical services, the pharmacy shall:

1. Operate under a valid retail and/or institutional permit issued by the Board of Pharmacy of the State of New Jersey or by the board of pharmacy of the state in which the pharmacy is located. A pharmacy operating under an out- of-State institutional permit may not participate as an approved provider in the New Jersey Medicaid or NJ FamilyCare program; and
2. File an application and sign an agreement with the Division of Medical Assistance and Health Services.

i. Upon sale or other change of ownership of an approved pharmacy, the agreement is automatically terminated. To execute a new agreement to participate in the New Jersey Medicaid and NJ FamilyCare programs, the new owner(s) shall apply to the Division of Medical Assistance and Health Services, Department of Human Services, by contacting the Provider Enrollment Unit (see N.J.A.C. 10:49 Administration Chapter, Enrollment Process) or the fiscal agent Provider Enrollment Unit (see Appendix D, Fiscal Agent Billing Supplement).

3. To enroll as a Medicaid and NJ FamilyCare provider of pharmaceutical services, a pharmacy shall contact the fiscal agent Provider Enrollment Unit (see Appendix D, Fiscal Agent Billing Supplement).

(c) Requirements for approval as a provider of parenteral nutrition and/or intravenous therapy are as follows:

1. In addition to the requirements for approval as a pharmacy provider listed under (b) above, a pharmacy which supplies parenteral nutrition and/or intravenous therapy shall:

i. Comply with all the requirements of N.J.A.C. 13:39; or

ii. Comply with similar applicable requirements of the state in which the applicant is located and submit a copy of the requirements of that state when applying for participation. A copy of N.J.A.C. 13:39 is available from West Group at 1-800-808-WEST.

2. Parenteral nutrition and/or intravenous therapy may be provided by either a pharmacy/medical supplier or a medical supplier approved to provide those services by the New Jersey Medicaid or NJ FamilyCare program; however, billing for the ancillary supplies

associated with parenteral nutrition and/or intravenous therapy are subject to the requirements of the Medical Supplier Chapter, N.J.A.C. 10:59.

i. "Ancillary supplies" means medical supplies and/or durable medical equipment which are medically necessary to facilitate administration of parenteral or intravenous therapy.

(d) Any new pharmacy, or any purchaser of an existing pharmacy possessing a valid permit described in (b)1 above, that has applied for approval as a provider of pharmaceutical services in the Medicaid, NJ FamilyCare and/or WFNJ/GA FFS programs may also apply for issuance of a temporary provider number. The temporary provider number, if issued by DMAHS, shall be effective on the date of issuance of the pharmacy permit, and shall be valid for up to 90 days. The temporary provider number may be utilized for the sole and limited purpose of accessing the point-of-sale system in order to determine whether Medicaid or NJ FamilyCare claims would be payable if the pharmacy is subsequently approved for provider status. However, no payments shall be made unless the application for provider status is approved and a permanent provider number is issued.

(e) DMAHS reserves the right to conduct prepayment and/or postpayment monitoring at any time of any pharmacy that is issued a temporary and/or permanent provider number.

10:51-2.3 Conditions for participation as a provider of pharmaceutical services

(a) All participating pharmacies shall provide complete prescription services, including injectables and injectable anti-neoplastic agents and compounding services, when allowable. Prescriptions and in-patient medication orders must be dispensed in compliance with all current existing Federal and State laws.

(b) All drugs must be prescribed.

1. "Prescribed drugs" mean simple or compound substances or mixtures of substances prescribed for the cure, mitigation, or prevention of disease, or for health maintenance that are:

i. Prescribed by a practitioner licensed or authorized by the State of New Jersey, or the state in which he or she practices, to prescribe drugs and medicine within the pharmacist's license and practice;

ii. Dispensed by licensed pharmacists in accordance with regulations promulgated by the New Jersey State Board of Pharmacy, N.J.A.C. 13:39; and

iii. Dispensed by licensed pharmacists on the basis of a written prescription and/or in-patient medication order that is recorded and maintained in the pharmacist's records.

(c) Participating pharmacies shall permit properly identified representatives of the Division of Medical Assistance and Health Services to:

1. Inspect written prescriptions and/or in-patient medication orders on file;
2. Audit records pertaining to covered persons;
3. Inspect private sector records, where deemed necessary to comply with the Federal regulations to determine a pharmacy's usual and customary charge to the public;

i. Information pertaining to the patient's name, address, and prescriber will remain confidential within the limits of the law. Only the following items may bereviewed:

(1) Drug name;
(2) Quantity dispensed;
(3) Price;
(4) Prescription number (for reference purposes only); and
(5) Date dispensed; and

4. Inspect records of purchases of covered drugs for which claims have been made for reimbursement.

10:51-2.4 Program restrictions affecting payment of prescribed drugs

(a) The choice of prescribed drugs shall be at the discretion of the prescriber within the limits of applicable laws. However, the prescriber's discretion is limited for certain drugs. Reimbursement may be denied if the requirements of the following rules are not met:

1. Covered and non-covered pharmaceutical services as listed in N.J.A.C. 10:51-2.10 and 2.11, respectively;

2. Quantity of medication (see N.J.A.C. 10:51-2.12);

3. Pharmaceutical services requiring pharmacist intervention as part of the Medicaid/NJ FamilyCare prospective drug utilization review (PDUR) program (see N.J.A.C. 10:51-2.23);

4. Dosage and directions (see N.J.A.C. 10:51-2.13);

5. Prescriptions and in-patient medication orders rendered by telephone or technological devices (see N.J.A.C. 10:51-2.14);

6. Changes or additions to the original prescription or in-patient medication order (see N.J.A.C. 10:51-2.15);

7. Prescription refill (see N.J.A.C. 10:51-2.16);

8. Prescription Drug Price and Quality Stabilization Act (N.J.S.A. 24:6E- 1 et seq.) (see N.J.A.C. 10:51-2.17);

i. Products listed in the current New Jersey Drug Utilization Review Council (DURC) Formulary (hereafter referred to as "the Formulary"), and all subsequent revisions, distributed to all prescribers and pharmacists; and

ii. Non-proprietary or generic dispensing (see N.J.A.C. 10:51-2.9);

9. Federal regulations (42 CFR 447.301, 331-334) that set the aggregate upper limits on payment for certain multi-source drugs if Federal Financial Participation (FFP) is to be made available. The limit applies to all "maximum allowable cost" drugs (see N.J.A.C. 10:51-2.5, Basis of payment);

10. Drug Efficacy Study Implementation (DESI): "Less than effective drugs" subject to a Notice of Opportunity for Hearing (NOOH) by the Federal Food and Drug Administration (see N.J.A.C. 10:51-2.18 and listing of DESI drugs in Appendix A);

11. Drug Manufacturers' Rebate Agreement with the Health Care Financing Administration of the United States Department of Health and Human Services (see N.J.A.C. 10:51-2.19);

12. For claims with service dates on or after July 1, 1998, all drugs prescribed for the treatment of impotency shall be limited to male beneficiaries over the age of 18 years and to four treatments per month; and

13. For claims with service dates on or after August 1, 1998, prescribers shall write "Diagnosis of Impotency" on the face of any prescription for impotency drugs. Claims for such prescriptions without this written statement shall be subject to recoupment by the State of New Jersey.

10:51-2.5 Basis of payment

(a) This section provides a summary of the elements involved in the calculation of the payment of a legend drug. The elements include the following:

1. Program restrictions affecting reimbursement for the dispensing of drugs as listed in N.J.A.C. 10:51-2.4;

2. Price information as supplied from a reference drug file subcontracted for this purpose by the fiscal agent and accepted by the Division as the primary source of pricing information for the New Jersey Medicaid Management Information System (NJMMIS). The drug price or ingredient cost shall not exceed the lower of the average wholesale price as supplied by the reference drug file contractor; the provider's usual and customary charge; or the drug's Maximum Allowable Cost, if applicable (see (b) below);

i. The NJMMIS reference drug file is updated periodically by the fiscal agent based upon data supplied by First Data Bank (FDB). The update process provides the fiscal agent with current data to include changes in product description. Providers are made aware of therapeutic indications for various classes of drugs by product literature distributed by drug manufacturers and by various trade publications. Based on market information, providers can determine whether a product's therapeutic classification meet the criteria specified in N.J.A.C. 10:51-2.10 (Covered pharmaceutical services).

3. Federal regulations (42 CFR 447.301, 331-334) that set the aggregate upper limits on payment for certain covered drugs in the pharmaceutical program. The New Jersey Medicaid and NJ FamilyCare programs refers to these upper limits as the "maximum allowable cost" (see (b) below); and

4. The provider's usual and customary charge for legend drugs (see (c) below), contraceptive diaphragms and legend devices.

(b) Payment for legend drugs, contraceptive diaphragms, and reimbursable legend devices, is based upon the maximum allowable cost. This means the lower of the upper payment limit price list (MAC price) as published by the Federal government or the average wholesale price (AWP). See Appendix B for the listing of MAC drugs.

1. Maximum allowable cost is defined as:

i. The MAC price for listed multi-source drugs published periodically by the Centers for Medicare and Medicaid Services (CMS) of the United States Department of Health and Human Services; or

ii. For legend drugs not included in (b)1i above, the Estimated Acquisition Cost (EAC), which is defined as the average wholesale price (AWP) listed for the package size (billed to the New Jersey Medicaid or NJ FamilyCare program), in current national price compendia or other appropriate sources (such as the First Data Bank (FDB) reference drug file contractor), and their supplements, minus regression category or discount.

2. For information about discounts, see N.J.A.C. 10:51-2.6.

3. If the published MAC price as defined in (b)1i above is higher than the maximum allowable cost which would be paid as defined in (b)1ii above, then (b)1ii above shall apply.

(c) For claims with service dates on or after the July 15, 1996, the maximum cost for each

eligible prescription claim not covered by the Maximum Allowable Cost price, as defined in N.J.A.C. 10:51-2.5(b)1i is based on the average wholesale price (AWP) of a drug, as defined in (b)1ii above, less a discount of 10 percent.

(d) The maximum charge to the New Jersey Medicaid program for pharmaceutical services provided in a nursing facility, including the drug cost and related capitation fee, shall be equal to the lower of:

1. MAC/EAC plus capitation fee, as described in N.J.A.C. 10:51-2.7; or
2. A provider's usual and customary charge for long-term care pharmacy services which is defined as the charge for legend drugs, including drug costs and related pharmaceutical services provided to non-Medicaid residents in the same facility, based on terms within the same contractual agreement with the facility.

(e) Providers of pharmaceutical services in nursing facilities are required, upon request by the Division of Medical Assistance and Health Services (DMAHS) or its authorized agent, to provide documentation supporting their usual and customary charges, including any relevant contracts and/or agreements related to similar services.

10:51-2.6 Discounts

For claims with service dates on or after July 15, 1996, the discount shall be 10 percent for each eligible prescription claim not covered by the Maximum allowable cost price.

10:51-2.7 Prescription dispensing fee (capitation)

(a) The New Jersey Medicaid and NJ FamilyCare programs capitate the dispensing fee for each prescription for beneficiaries in Medicaid-approved nursing facilities in accordance with the total number of Medicaid and NJ FamilyCare fee-for-service beneficiary days in the facility(ies) serviced by the pharmacy. Additional dispensing fees (add-ons) per prescription shall be given to pharmacy providers who provide the following levels of services: Pharmacies with institutional permits shall be reimbursed as defined in (a) above, except that the daily per beneficiary capitation fee shall be 75 percent of the fee for pharmacies with retail permits.

1. Twenty-Four Hour Unit Dose Service: Pharmacies with retail permits dispensing medication in a dispensing system in which a 24-hour supply of unit dose oral medication, both solid (for example, tablets, capsules) and liquid formulations, is delivered for each beneficiary daily, shall be reimbursed the cost of all reimbursable legend medication plus a fee of $0.656 per beneficiary day.

i. Exception: Certain liquid medications that are supplied in concentrate form only and are administered by drop dosage cannot be supplied in a 24-hour dose.

2. Modified Unit Dose Service: Pharmacies with a retail permit dispensing medication in a dispensing system in which up to a one-month supply of oral unit dose solid medication is delivered for each beneficiary (for example, unit dose solids, "bingo" card), shall be reimbursed the cost of all reimbursable legend medication plus a fee of $0.544 per beneficiary day.

3. Traditional Service: Pharmacies with a retail permit dispensing medication in a dispensing system in which a maximum one-month supply of medication is delivered monthly for each beneficiary shall be reimbursed the cost of legend medication plus a fee of $0.487 per

beneficiary day.

4. Computerized Service: Pharmacies which provide ancillary computerized services, such as, but not limited to, continuously updated computerized beneficiary profiles, clinical records (med sheets and physicians' orders on at least a monthly basis), etc., receive an added increment of $0.05 per beneficiary day, thereby making the total fee $0.706, $0.594 or $0.537 depending upon the dispensing system used.

(b) Price information is supplied from a reference drug file subcontracted for this purpose by the fiscal agent and accepted by the Division as the primary source of pricing information for the New Jersey Medicaid Management Information System. The calculated price shall not exceed the lower of the average wholesale price (AWP) or the Federal Fund Participation Upper Limit (FFPUL) as supplied by the reference drug file contractor.

(c) In order to receive any or all of the above increments, the provider shall certify annually to the Division on Form FD-70, that the service(s) as defined in (a) above, are being provided and/or that the provider is entitled to the impact increment as defined in (a) above.

1. Each claimed increment is subject to audit and retroactive recovery with appropriate penalties, if warranted, if the New Jersey Medicaid or NJ FamilyCare program determines that the provider was not entitled to reimbursement for them.

(d) When a nursing facility changes its servicing pharmacy provider, the new pharmacy provider must notify the fiscal agent so that the provider file of the New Jersey Medicaid Management Information System (NJMMIS) may be updated. The following information is required in writing:

1. A copy of the agreement between the servicing pharmacy provider and the nursing facility (Appendix G, incorporated herein by reference);

2. The provider number of the servicing pharmacy;

. The effective date of the change in servicing pharmacy provider if not clearly indicated in the agreement between the servicing pharmacy provider and the nursing facility;

4. The name and address of the previous servicing pharmacy provider for the nursing facility;

5. The level of service to be provided (for example: traditional, modified unit dose, or 24-hour unit dose); and

6. A statement indicating the provision of ancillary computerized services or recordkeeping for the nursing facility.

10:51-2.8 Compounded prescriptions

(a) Compounded prescriptions may be reimbursed by the Medicaid or NJ FamilyCare program. Compound prescriptions are extemporaneously prepared mixtures of an active ingredient or ingredients and/or a pharmaceutical excipient or excipients and are dispensed by approved providers.

1. Acceptable pharmaceutical excipients which do not contribute therapeutically to a compound include, but are not limited to hydrophilic ointment, petrolatum, aquaphor, eucerin cream, phenol, menthol, resorcinol, caffeine, talc, simple syrup, aromatic elixir distilled water, and glycerin.

(b) Claims for compounded prescriptions may be manually or electronically submitted to the fiscal agent through a point-of-sale (POS) claims adjudication system approved by the Division. (See N.J.A.C. 10:51-2.22)

1. A compounded prescription is indicated by the provider by the use of the "compounded drug" indicator field on a manual claim or in a similar field in the EMC claim format.

(c) Reimbursement for compounded prescriptions shall be based on the cumulative cost of the active ingredient(s), as described in N.J.A.C. 10:51- 2.5, and/or pharmaceutical excipient(s).

(d) For compounded prescriptions without an active ingredient(s), reimbursement is based on the cumulative cost of the pharmaceutical excipient(s).

1. For pharmaceutical excipients costing less than $0.25, the provider may charge Medicaid or NJ FamilyCare $0.25 for each ingredient.

2. Reimbursement for compounded prescriptions without an active ingredient(s) shall be provided under a common drug code assigned by DMAHS.

(e) Reimbursement for compounded prescriptions submitted manually or as an EMC claim is calculated based on the ingredient cost, as described in N.J.A.C. 10:51-2.5, of the most costly active ingredient.

(f) The maximum charge for a compounded prescription must not exceed the limits set forth in N.J.A.C. 10:51-2.12.

(g) Restrictions on payments for compounded prescriptions are as follows:

1. All legend and non-legend (OTC) ingredients which are contained in compounded prescriptions must be covered by a manufacturer rebate agreement (see N.J.A.C. 10:51-2.19). If the labeler code of any single ingredient is not manufactured by an approved manufacturer, the compounded prescription is not covered. Chemical ingredients without NDC codes are excluded.

2. All non-legend ingredients which are contained in compounded prescriptions shall be among those covered by the Medicaid or NJ FamilyCare program. If a non-legend drug is not listed as covered in N.J.A.C. 10:51-2.10, the compounded prescription shall not be covered.

3. All legend ingredients which are contained in compounded prescriptions shall be among those covered by the Medicaid or NJ FamilyCare program. If a legend drug is a DESI (Drug Efficacy Study Implementation, see N.J.A.C. 10:51-2.18) drug, the compounded prescription shall not be covered.

4. Compounded prescriptions containing drugs not eligible for reimbursement under N.J.A.C. 10:51-2.11 shall not be covered.

10:51-2.9 Non-proprietary or generic dispensing

When medication is prescribed by its non-proprietary or generic name, the pharmacist shall dispense the least expensive, therapeutically effective equivalent product available, preferably one listed in the DURC Formulary. The labeler code and drug product code of the actual

product dispensed must be reported on the claim form. The package size code reported may differ from the stock package size used to fill the prescription.

10:51-2.10 Covered pharmaceutical services

(a) All covered pharmaceutical services shall be provided within the scope of N.J.A.C. 10:49 (Administration) and this Chapter, and billed to the fiscal agent on the claim form or other approved billing method. (See Appendix, Fiscal Agent Billing Supplement).

(b) Covered pharmaceutical services include:

1. Prescribed legend drugs (for their medically accepted indication) as defined in Section 1927(k)(6) of Social Security Act. "Legend drugs" mean those drugs whose labels include the legend statement "Caution: Federal Law Prohibits Dispensing Without a Prescription."

10:51-2.11 Non-covered pharmaceutical services

(a) The following classes of prescription drugs or conditions shall not be covered under the New Jersey Medicaid or NJ FamilyCare program:

1. Prescriptions which are not for medically accepted indications as defined in Section 1927(k)(6) of the Social Security Act;
2. Antiobesics and anorexiants when used in treatment of obesity;
3. Drug products for which adequate and accurate information is not readily available, such as, but not limited to, product literature, package inserts and price catalogues;
4. Experimental drugs;

i. Exception: Drugs available only for treatment through an Investigational New Drug (IND) application may be prior authorized;

5. Medication furnished by a prescriber or an employee of a prescriber;
6. Medication prescribed for hospital inpatients;
7. Non-legend drugs;
8. Prescriptions and in-patient medication orders written and/or dispensed with nonspecific directions;
9. Food supplements, milk modifiers, infant formulas, therapeutic diets, special liquid or powdered diets used in the treatment of obesity;
10. Methadone in any form (tablets, capsules, liquid, injectables, or powder) when used for drug detoxification or addiction maintenance;
11. Drug products for which final orders have been published by the Food and Drug Administration, withdrawing the approval of their new drug application (NDA);
12. Drugs or drug products not approved by the Food and Drug Administration, when such approval is required by Federal law and/or regulation;
13. Radiopaque contrast materials (for example, Telepaque);
14. Drugs for which Federal Financial Participation (FFP) is not available, including:

i. Drug Efficacy Study Implementation (DESI) drugs and identical, similar and related drugs (see N.J.A.C. 10:51-2.18); and

ii. Drugs not covered by rebate agreements as defined in Section 4401 of OBRA '90 and Section 1927(a) of the Social Security Act (see N.J.A.C. 10:51-2.19);

15. Any bundled drug service (see N.J.A.C. 10:51-2.20); and

16. Preventive vaccines, biologicals and therapeutic drugs distributed to hospital clinics and/or community health centers by the New Jersey Department of Health and Senior Services.

(b) Otherwise reimbursable products shall be excluded from payment, under the following condition(s):

1. Products whose costs are found to be in excess of defined costs outlined in N.J.A.C. 10:51-2.5, basis of payment;

2. Drug products in dosage forms whose labeling, prescription or promotional material indicate the primary use is cosmetic in nature; for example, hair restoration;

3. Drug products available in unit-dose packaging and dispensed to residents in a boarding home or residential care setting or other community type setting. Other community type setting shall not include certain assisted living settings, including assisted living residences (ALRs), comprehensive personal care homes (CPCHs) and alternative family care (AFC) homes licensed by the Department of Health and Senior Services.

i. Drug products commercially available only as a unit-dose packaged product are covered when not otherwise marketed as a chemically equivalent product. The potency of equivalent products may or may not equal the potency of the unit-dose packaged product; and

4. Drug products denied payment based on point-of-sale (POS) and prospective drug utilization review (PDUR) standards adopted by the Medicaid and NJ FamilyCare programs. (See N.J.A.C. 10:51-2.23)

10:51-2.12 Quantity of medication

When the quantity of a drug or medication is not indicated in writing by the prescriber, the pharmacy provider shall dispense an appropriate quantity of medication not to exceed a one month supply (see N.J.A.C. 10:51-2.16, Prescription Refill).

10:51-2.13 Dosage and directions

(a) Dosage and directions for use shall be included as part of all prescriptions or in-patient medication orders. Prescriptions or inpatient medication orders written and dispensed with no specific directions, such as "prn," "as directed" or "ad lib," etc. are not eligible for reimbursement. Specific directions such as "1 tablet 4 times a day PRN" are required.

1. Exceptions:

i. Topical preparations including ophthalmic and otic drops and ointments;

ii. Aerosol inhalers; and

iii. Nitroglycerin.

2. For all oral medication and injectables, the number of days the medication should last, based on the prescriber's directions of use, shall be entered in the "Days Supply" field on the pharmacy claim form or similar field in the EMC claim format.

(b) The number of days reported for the days supply dispensed on the pharmacy claim or in the appropriate field on the EMC claim must accurately reflect the intended duration of drug utilization, or a reasonable estimation of a drug's intended duration of use when a drug's dosage is unrelated to a specific days supply.

10:51-2.14 Prescriptions and in-patient medication orders rendered by telephone or technological devices

(a) Telephone rendered and/or technologically transmitted (for example: Fax) original prescriptions shall be permitted in accordance with all applicable Federal and State laws and regulations.

(b) For purposes of reimbursement, a telephone rendered and/or a technologically transmitted (for example, Fax) authorization to refill an original prescription is considered a new prescription or in-patient medication order and requires a new prescription number. Stamping or writing a new number on the original prescription or in-patient medication order does not constitute a new prescription under the Medicaid or NJ FamilyCare program.

(c) When a prescriber chooses not to allow product interchange on a telephone rendered original prescription or in-patient medication order, the statement "Substitution not permitted by prescriber-telephoned Rx" plus the pharmacist's full signature next to or below the statement, shall appear on the medication order. A rubber stamp bearing the statement is acceptable.

(d) When a prescriber chooses to certify "Brand Medically Necessary" on a telephone rendered original prescription or in-patient medication order for a product included on the Federal MAC list, a written signed prescription or in- patient medication order containing the certification, shall be sent to the pharmacist within seven days of the date of the telephone order. The written in-patient medication order shall be retained by the pharmacist as the original prescription. Failure to comply will result in the payment for that prescription being reduced to the MAC reimbursement level.

10:51-2.15 Changes or additions to the original prescription or in-patient medication order

Changes or additions to the original prescription or in-patient medication order, when approved by the prescriber, shall be clearly indicated (including date and time) and signed by the dispensing pharmacist. No changes (for example, dosage, quantity, number of refills, days supply, etc.) are permitted on the original prescription order after the claim is submitted for payment.

10:51-2.16 Prescription refill

(a) Refills are not allowed.

(b) For purposes of reimbursement, an order for continuation of medication shall be considered a new prescription requiring a new written prescription and new prescription number.

10:51-2.17 Prescription Drug Price and Quality Stabilization Act

(a) The Prescription Drug Price and Quality Stabilization Act, N.J.S.A. 24:6E-1 et seq., shall apply to the New Jersey Medicaid and NJ FamilyCare programs. This law requires that every

prescription blank contain the statements "Substitution Permissible" and "Do Not Substitute." The prescriber shall initial one of the statements in addition to signing the prescription blank.

1. When the prescriber does not initial "Substitution Permissible" or the "Do Not Substitute" statement on a prescription or in-patient medication order for a drug product listed in the DURC Formulary, the pharmacist shall substitute from the list of interchangeable products and bill Medicaid or NJ FamilyCare accordingly.

2. When the prescriber initials "Substitution Permissible" on the prescription blank, the pharmacist shall dispense and bill Medicaid or NJ FamilyCare, as appropriate, for one of the less expensive products listed in the DURC Formulary as interchangeable with the brand name prescribed. The Medicaid or NJ FamilyCare fee-for-service beneficiary must accept the interchangeable product unless the beneficiary is willing to pay the pharmacy's full, usual and customary price. If that occurs, the pharmacist shall so note on the prescription blank and no claim shall be submitted to Medicaid or NJ FamilyCare.

3. When a prescriber authorizes, in accordance with (b) below, the dispensing of a brand MAC drug, the pharmacist shall indicate the prescriber's preference by indicating "Medical Certification" on the claim form or the similar field in the EMC claim format and shall dispense and bill Medicaid or NJ FamilyCare, as appropriate, for the prescribed product. Reimbursement will be the estimated acquisition cost (EAC) (see N.J.A.C. 10:51-2.5) plus applicable dispensing fee or the usual and customary charge, whichever is less for that product (See Appendix D, Fiscal Agent Billing Supplement for instructions about the claim form and Appendix E regarding the proper EMC claim format).

4. When the prescriber orders by the generic name, the DURC Formulary (see N.J.A.C. 10:51-2.4) does not apply. The pharmacist shall dispense the least expensive, therapeutically effective product available to him or her at the time of dispensing. The product need not necessarily be from the list of interchangeable products.

(b) Federal regulations prescribe the aggregate upper limit, for which Federal Financial Participation (FFP) is available, that Medicaid or NJ FamilyCare-Plan A may reimburse for certain multi-source drugs. This limit shall also apply to NJ FamilyCare-Plans B and C. The limit shall apply to all listed MAC drugs (see Appendix B) unless the prescriber indicates in his or her own handwriting on each written prescription or in-patient medication order or follow-up written prescription or in-patient medication order to a telephone- rendered prescription or technologically transmitted, (for example, Fax) (see N.J.A.C. 10:51-2.9) the phrase "Brand Medically Necessary." The Federal regulation requires a handwritten statement and does not permit the use of alternatives such as a check-off box, initials or prescriber's signature, next to a preprinted statement "Do Not Substitute," nor does it allow a hand written statement "Do Not Substitute." For purposes of reimbursement, the physician's override capability under N.J.S.A. 24:6E-1 does not apply to drugs which have a Federal MAC limit.

(c) Blanket authorization denying substitutions shall not be permitted. Each prescription or in-patient medication order shall state "Brand Medically Necessary" in the prescriber's own handwriting. For non-MAC drugs, each prescription order shall follow the requirements of N.J.S.A. 24:6E-1 et seq. (see (a) above).

(d) For claims with service dates on or after July 1, 1999, the pharmacist shall dispense the least expensive, therapeutically effective nutritional supplement or specialized infant formula, at the time of dispensing, unless the prescriber indicates in his or her own handwriting on each written prescription or follow-up written prescription to a telephone rendered prescription the phrase "Brand Medically Necessary."

(e) The dispenser must always report the actual labeler code and drug product code of the drug dispensed. The package size code reported may differ from the stock package size used to fill the prescription.

10:51-2.18 Drug Efficacy Study Implementation (DESI)

(a) "Less than effective drugs" are subject to a Notice of Opportunity for Hearing (NOOH) by the Food and Drug Administration (FDA).

1. Reimbursement is not available for the purchase or administration of any drug product that meets all of the following conditions:

i. The drug product was approved by the Food and Drug Administration (FDA) before October 10, 1962;

ii. The drug product is available only through prescription;

iii. The drug product is the subject of a notice of opportunity for hearing issued under Section 505(e) of the Federal Food, Drug, and Cosmetic Act and published in the Federal Register on a proposed order of FDA to withdraw its approval for the drug product because it has determined that the product is less than effective for all its labeled indications; and

iv. The drug product is at present the subject of an efficacy review study performed by FDA (see 21 CFR 310.6 including all subsequent amendments and supplements). The FDA efficacy review potentially can determine justification for a drug product's medical need. If a drug product fails this review, the product is classified as a DESI drug.

2. Reimbursement is not available for the purchase or administration of any drug product that is identical, related or similar, as defined in 21 CFR 310.6 (including all subsequent amendments and supplements), to a drug product that meets the conditions of (a) above.

3. The initial identification of drugs and related drug products classified as "less than effective" by the FDA pending outcome of the NOOH appears at 21 CFR 310.6. Subsequent revisions which are adopted shall appear in the Federal Register.

10:51-2.19 Drug manufacturers' rebate agreement

(a) In order for legend drug products to be reimbursed by the New Jersey Medicaid or NJ FamilyCare program, manufacturers must have in effect a rebate agreement pursuant to Section 4401 of OBRA 1990 and Section 1927 et seq. of the Social Security Act.

(b) Price information is supplied from a reference drug file subcontracted for this purpose by the fiscal agent and accepted by the Division as the primary source of pricing information for the New Jersey Medicaid Management Information System (NJMMIS). The calculated price shall not exceed the lower of the average wholesale price (AWP) or the Federal Fund Participation Upper Limit (FFPUL) as supplied by the reference drug file contractor.

10:51-2.20 Bundled drug service

(a) "Bundled drug service" means a drug or service that is marketed or distributed by the manufacturer or distributor as a combined package which includes in the cost the drug product and ancillary services such as, but not limited to, case management services and laboratory testing.

(b) Bundled drug service shall not be eligible for reimbursement by the New Jersey Medicaid or NJ FamilyCare program.

1. This provision may be waived at the discretion of the Commissioner if the Commissioner determines that a bundled drug service is less than or equal to the total cost of the unbundled components if reimbursed separately; or

2. The Commissioner may waive the provisions for reasons of medical necessity for a bundled drug or in accordance with terms approved by the Department as follows:

i. Those instances where discontinuation, withdrawal, or elimination of the use of the bundled drug by someone who has been receiving a bundled drug would result in the deprivation of the life saving or life prolonging benefits of the drug or would cause potential harm or serious exacerbation of the illness being treated; or

ii. Those instances where use of the bundled drug has shown marked improvement in the beneficiary's clinical status reflected in alleviation of symptoms, and elevation of level of function and independence.

(c) In order to determine eligibility for reimbursement, manufacturers or distributors of a bundled drug service shall submit complete product information, including the cost to the programs of the total bundled drug service, discrete costs of each component of the bundled drug service, cost benefit analyses, and other information as requested by the Department, to the Chief Pharmaceutical Consultant, Division of Medical Assistance and Health Services, Mail Code #20, PO Box 712, Trenton, New Jersey 08625-0712.

1. If the Commissioner determines that a bundled drug is eligible for reimbursement under this section, New Jersey Medicaid or NJ FamilyCare fee-for-service beneficiaries shall receive or continue to receive the bundled drug service if prior authorization is requested and approved. Prior authorization shall be obtained by completing the appropriate "Request for Authorization Form" requesting medication management authorization and providing sufficient documentation to establish that it is medically necessary to continue the bundled drug services. Mail all the information to:

Assistant Director
Office of Utilization Management
Mail Code #15
PO Box 712
Trenton, NJ 08625-0712

10:51-2.21 Claims submission

(a) Based on the level of service provided by an approved pharmacy to a nursing facility, a

provider may choose to:

1. Submit a properly completed hard copy pharmacy claim form approved by the New Jersey Division of Medical Assistance and Health Services (DMAHS).

2. Submit an electronic media claim (EMC) by modem, diskette or magnetic tape in an approved electronic format that complies with the National Council Prescription Drug Program (NCPDP) standards Version 5.1 and Version 1.1, as amended and supplemented, incorporated herein by reference. The Council's address is 4201 North 24th Street, Suite 365, Phoenix, Arizona 85016.

i. In order for a pharmacy provider to be eligible to submit an EMC claim to the Medicaid NJ FamilyCare programs, a pharmacy provider or vendor of EMC services shall complete the "New Jersey Medicaid Provider Electronic Billing Agreement."

ii. The completed agreement shall be submitted to the fiscal agent and approved by the Division of Medical Assistance and Health Services.

iii. The pharmacy provider or vendor of EMC services shall submit electronic media claims under an approved submitter identification number and comply with EMC requirements contained in the EMC Manual, Appendix E, incorporated herein by reference.

iv. For the purposes of this subchapter, all electronically submitted claims, including POS claims, shall commonly be referred to as EMC claims.

3. Enter into an agreement with a point-of-sale (POS) intermediary or directly provide a similar telecommunication network approved by DMAHS to submit claims to the fiscal agent for adjudication. POS claims require an approved electronic format which complies with the National Council Prescription Drug Program standards, Version 5.1 and Version 1.1, as amended and supplemented, incorporated herein by reference. The Council's address is 4201 North 24th Street, Suite 365, Phoenix, Arizona 85016.

i. The approved POS intermediary or provider established network shall enter into an agreement with the State of New Jersey to provide on-line telecommunication services, including transmission of pharmacy claim detail data, access to the fiscal agent's POS computer and return of adjudicated claim data to the provider.

(b) A properly completed claim form or a properly formatted electronic media claim (EMC) may be submitted to the fiscal agent, or transmitted by an approved POS intermediary or provider established telecommunication network to the fiscal agent for claims adjudication.

1. A single claim form shall be completed manually or by computer or an EMC claim shall be transmitted in the approved EMC format for each Medicaid or NJ FamilyCare prescription dispensed. See Appendix D, Fiscal Agent Billing Supplement, for instructions concerning the completion and submission of the specified claim form, and Appendix E regarding the proper EMC claim format;

2. All claim forms and EMC claims must contain the National Drug Code (NDC) of the actual drug dispensed. The 11-digit NDC has three components. The first five digits are the manufacturer's labeler code, the next four digits are the product code and the final two digits are the package size code. For claim submission, leading zeros shall be included in all fields. For example, 00003-0234-01.

i. The dispenser shall always report the actual labeler code and drug product code of the drug dispensed. The package size code reported may differ from the actual stock package size code

reported on the claim.

3. All Medicaid or NJ FamilyCare fee-for-service pharmacy claims submitted to the fiscal agent for payment consideration shall be adjudicated based on the outcome of established POS and PDUR edits, regardless of the mode of claim submission.

10:51-2.22 Point-of-sale (POS) claims adjudication system

(a) Pharmacies providing traditional pharmacy services, as described in N.J.A.C. 10:51-2.7, to nursing facilities may be submitted through a POS system and adjudicated by the State's fiscal agent on-line and in real-time. The POS system is an alternative to other methods of claim submission, including magnetic tape, diskette and paper claims. The pharmacist would be required to enter pharmacy claim detail data into a computer or POS device and transmit this data to the fiscal agent over a dedicated telephone line. Regardless of the method of claim submission, all claims will go through all New Jersey Medicaid Management Information System (NJMMIS) claims processing edits and the claims will be processed to determine their payment disposition (for example, paid or denied).

1. Pharmacy services provided to nursing facility and residential care residents utilizing 24 hour unit-dose or modified unit-dose drug delivery systems are precluded from the POS system.

(b) In order for a Medicaid or NJ FamilyCare-approved pharmacy provider, in accordance with N.J.A.C. 10:51-2.3, to submit pharmacy claims through a POS system, the provider shall enter into an agreement with a POS intermediary or shall directly provide a similar telecommunications network approved by the New Jersey Division of Medical Assistance and Health Services.

1. In order to become an approved POS intermediary or provider established network, a firm shall notify the Division at the following address:

Division of Medical Assistance and Health Services
Office of Information Systems
Mail Code #4
PO Box 712
Trenton, New Jersey 08625-0712
(Telephone: 609-588-2802)

2. The Division shall send the interested party a summary of the program and instructions on how to submit an application.

3. The Division shall consider the following in evaluating an application:

i. The applicant's general approach and plans to meet the requirements of the POS project;

ii. The applicant's detailed approach and plans to meet the requirements of the POS project;

iii. The applicant's documented qualifications, expertise, and experience on similar projects;

iv. The applicant's proposed staff's documented qualifications, expertise, and experience on similar projects; and

v. The applicant's adherence to the requirements of the Health Care Financing Administration.

(c) A POS participating pharmacy or intermediary shall supply the computer hardware or POS device and required software to generate electronic media claims (EMC) in a format consistent with POS standards adopted by the New Jersey Medicaid and NJ FamilyCare programs.

(d) A POS participating pharmacy or intermediary shall supply modem capability required to properly transmit claim detail data to the approved POS intermediary or to participate in the provider established telecommunication network.

(e) All Medicaid and NJ FamilyCare pharmacy providers choosing to submit claims through the POS system shall submit claims in the approved electronic format, and transmit these claims on-line for adjudication by the fiscal agent's POS computer system.

1. Pharmacy services provided to nursing facility and residential care residents utilizing 24 hour unit-dose or modified unit-dose or modified unit- dose drug delivery systems are precluded from the POS system.

(f) Claim data requirements for electronic media claims (EMC) generated by POS participating pharmacies include:

1. The first five alpha characters of the last name and the first three alpha characters of the Medicaid or NJ FamilyCare beneficiary's first name;
2. The 12-digit Medicaid or NJ FamilyCare identification number;
3. The date of birth, if applicable;
4. The nursing facility residency indicator;
5. The date of service or dispense date;
6. The pharmacy prescription number;
7. The actual 11 digit National Drug Code (NDC) of the drug dispensed;
8. The metric quantity dispensed;
9. The days supply;
10. The prescriber's provider service number;
11. The third party payment, if applicable;
12. The provider's usual and customary charge;
13. The pharmacy provider number; and
14. The carrier code(s), if applicable.

(g) Additional supplementary data requirements, which are claim specific, include:

1. The medical certification indicator;
2. The other insurance indicator, if applicable;
3. The compound drug indicator; and
4. The carrier code(s), if applicable.

(h) A POS-participating pharmacy or intermediary shall be required to implement software changes requested by the Division within 60 days of notification of such a request to ensue the generation of electronic claims acceptable to the Division.

(i) Pharmacy software must have the capability to display on-line adjudicated claim data

returned to the pharmacy by the fiscal agent, including:

1. Payment disposition;
2. Error code messages; and
3. Claim pricing data, including drug cost reimbursement, dispensing fee and applicable copayment amounts.

(j) Pharmacy software must provide the pharmacy with the capability of claim reversal and resubmission, if required.

1. A pharmacy may initiate a claim reversal of a previously submitted pharmacy claim for a period of 12 months from the initial date of claim service.
2. Pharmacies are required to initiate claim reversals for those services in which the claim was generated and adjudicated to payment by the fiscal agent's POS computer and the service was not subsequently provided to a Medicaid or NJ FamilyCare fee-for-service beneficiary.

(k) Pharmacies are required to interact with prescribers and/or beneficiaries at POS to resolve matters related to on-line messages resulting from claim adjudication by the fiscal agent.

10:51-2.23 Prospective drug utilization review (PDUR) program

(a) The Division of Medical Assistance and Health Services has established a prospective drug utilization review (PDUR) program to assist pharmacy providers with monitoring drug utilization by Medicaid and NJ FamilyCare beneficiaries. As a component of the Medicaid and NJ FamilyCare point-of-sale (POS) claims adjudication system, the State's fiscal agent will review drug utilization based on claims submitted on-line and provide pharmacists with responses in real-time regarding utilization within PDUR standards recommended by the New Jersey Drug Utilization Review (DUR) Board. Similar responses related to EMC or paper claims processed by the New Jersey Medicaid Management Information System (NJMMIS) shall be received by pharmacies on the Remittance Advice statement.

1. PDUR standards approved by the Medicaid DUR Board shall be based on standards established by First Data Bank (FDB) as part of the FDB DUR information system. The FDB standards are incorporated herein by reference and may be obtained from First Data Bank, The Hearst Corp., 1111 Bayhill Dr., San Bruno, CA 94066.
2. PDUR standards adopted by the New Jersey Drug Utilization Review (DUR) Board shall be applied to all Medicaid and NJ FamilyCare pharmacy claims resulting from traditional pharmacy services provided in nursing facilities, regardless of the mode of claim submission.

(b) POS participating pharmacy providers shall be required to meet the conditions described in N.J.A.C. 10:51-2.23.

(c) In addition to POS responses related to adjudication of Medicaid or NJ FamilyCare pharmacy claims returned to the pharmacy, pharmacists shall be notified regarding drug utilization inconsistent with adopted PDUR standards which may include, but not be limited to:

1. Drug-drug interactions;
2. Maximum/minimum daily dosage;
3. Therapeutic duplication;

4. Drug-age conflicts;
5. Duration of therapy;
6. Drug-pregnancy precautions;
7. Drug-gender conflicts;
8. Under-usage; and
9. Weight-based.

(d) The PDUR program may apply adopted standards based on a severity index approved by the New Jersey DUR Board to determine appropriate pharmacist intervention and/or claim disposition (for example, payment or denial) of Medicaid or NJ FamilyCare fee-for-service pharmacy claims.

(e) Based on the severity of a potential PDUR conflict or interaction, pharmacists shall be required to consult with the beneficiary and/or prescriber to resolve matters indicated by PDUR messages returned by the POS system.

(f) The pharmacist intervention requirements related to the PDUR program are in addition to beneficiary interactions related to the "offer to consult" as described in N.J.A.C. 13:39-7.14, patient profile record system.

END OF SUBCHAPTER 2

SUBCHAPTER 3. CONSULTANT PHARMACIST SERVICES

10:51-3.1 Introduction

All services required of a consultant pharmacist in nursing facilities as stipulated in Federal and State statutes, rules and regulations, including, but not limited to, those listed in this subchapter, shall be provided.

10:51-3.2 Definition of consultant pharmacist

The term "consultant pharmacist" shall mean a pharmacist licensed by the New Jersey State Board of Pharmacy, and who meets the qualifications in N.J.A.C. 10:51-3.3.

10:51-3.3 Qualifications

Qualifications shall include holding a valid license as a registered pharmacist issued by the New Jersey State Board of Pharmacy.

10:51-3.4 Responsibilities

(a) The consultant pharmacist shall in cooperation and consultation with the nursing facility staff:

1. Assure that all drugs are dispensed, and in cooperation with the director of nursing, "shall assure all drugs" are administered in compliance with all Federal and State laws;
2. Establish and monitor the implementation of written policies and procedures, through the pharmaceutical services committee (pharmacy and therapeutics committee), to assure the safe use, storage, integrity, administration, control and accountability of drugs;
3. Assure that drug records are in order and an account of all controlled substances is maintained and reconciled;
4. Assure that the beneficiary's medication records are accurate, up to date, and that these records indicate that medications are administered in accordance with physicians' orders and established stop-order policies;
5. Assure that drugs, biologicals, laboratory tests, special dietary requirements and foods, used or administered concomitantly with other medication to the same beneficiary, are monitored for potential adverse reactions, allergies, rationality, drug evaluation, and laboratory test modifications, and that the physician is advised promptly of any recommended changes;
6. Assure that drugs prescribed for nursing facility beneficiaries are properly administered based on drug utilization standards common to the pharmacy profession, which may include, but not be limited to:
   i. Drug interactions;
   ii. Maximum/minimum daily dosage alerts;
   iii. Therapeutic duplication;
   iv. Drug age conflicts;
   v. Days supply alerts;
   vi. Drug-disease precautions; and
   vii. Drug-pregnancy precautions, if applicable.

7. Review the drug regimen (for example, dosage form, route of administration, time of administration) of each beneficiary at least monthly and report any irregularities pertaining to medications to the attending physician, medical director or director of nursing, as appropriate.

i. Irregularities in the administration of medications shall also be reported promptly to the director of nursing.

8. Report in writing at least quarterly to the pharmaceutical services committee (pharmacy and therapeutic committee) on the status of the facility's pharmaceutical services and staff performance as related to pharmaceutical services. This report shall include, but not be limited to, a summary of the review of each beneficiary's drug regimen and clinical record and the consultant pharmacist's findings and recommendations;

9. Assure there is maintained and available upon request from the Director of the Division of Medical Assistance and Health Services or his or her designee, documented records of the disposition, disposal or destruction of unused or discontinued drugs;

10. Serve as an active member of the pharmaceutical services committee (pharmacy and therapeutics committee) and infection control committee of the facility;

11. Provide, and document, in-service programs for the complete nursing staff. This training shall include, but not be limited to, registered nurses, licensed practical nurses, aides, and shall be given at least quarterly; and

12. Devote a sufficient number of hours to carry out these responsibilities, maintain a written record of activities, findings and recommendations.

END OF SUBCHAPTER 3

10:51-4.1 (Reserved)

END OF SUBCHAPTER 4

APPENDIX A

DRUG EFFICACY STUDY IMPLEMENTATION (DESI)

(Update of Drug Products and Known Related Drug Products that Lack Substantial Evidence of Effectiveness.)

Appendix A is a list of drugs that the Food and Drug Administration (FDA) has proposed to withdraw from the market. The list is updated periodically by the Centers for Medicare and Medicaid Services subsequent to published listing changes in the Federal Register, in accordance with 21 C.F.R. 310.6.

AGENCY NOTE: Appendix A is filed as a part of this chapter but is not reproduced in the New Jersey Administrative Code. When revisions are made to the Appendix A, replacement pages will be distributed to providers, placed on the website at www.njmmis.com and copies will be filed with the Office of Administrative Law. For a copy of the Appendix A, write to:

Unisys
PO Box 4801
Trenton, New Jersey 08650-4801

or contact:

Office of Administrative Law
Quakerbridge Plaza, Building 9
PO Box 049
Trenton, New Jersey 08625-0049

APPENDIX B

UPPER PAYMENT LIMITS FOR MAXIMUM ALLOWABLE COST (MAC) DRUGS

Appendix B lists the multiple source drugs which meet the criteria set forth in 42 CFR 447.301, 331-333 which is updated periodically by the Centers for Medicare and Medicaid Services subsequent to published listing changes in the Federal Register.

AGENCY NOTE: The Appendix B is filed as a part of this chapter but is not reproduced in the New Jersey Administrative Code. When revisions are made to the Appendix B, replacement pages will be distributed to providers, placed on the website at www.njmmis.com and copies will be filed with the Office of Administrative Law. For a copy of the Appendix B, write to:

Unisys
PO Box 4801
Trenton, New Jersey 08650-4801

or contact:

Office of Administrative Law
Quakerbridge Plaza, Building 9
PO Box 049
Trenton, New Jersey 08625-0049

APPENDIX C
STATE OF NEW JERSEY
DEPARTMENT OF HUMAN SERVICES
DIVISION OF MEDICAL ASSISTANCE AND HEALTH SERVICES
AND
DEPARTMENT OF HEALTH AND SENIOR SERVICES
PHARMACY PROVIDER CERTIFICATION STATEMENT

Pharmacy Name _____ Provider ID #_____
Address _____ Telephone (___) _____

SECTION I. FEE INCREMENTS ADDED TO BASIC DISPENSING FEE

1. Impact Allowance $0.15

This provider has a combined Medicaid/NJ FamilyCare/PAAD/ADDP/ CF/SGPD prescription volume (including LTCF Rxs) equal to or greater than 50 percent of the total Rx volume and qualifies for "Impact Allowance."

Actual Percentage: _____ ___ Yes ___ No

Note: If conditions for earning impact allowance change, the provider must notify Unisys, in writing, at PO Box 4804, Trenton, NJ 08650-4804, within 30 days of change, and must immediately cease adding the impact allowance increment to the basic dispensing fee. If the State determines that the provider has not met the impact allowance requirements, the State shall recover the total reimbursement for this increment, retroactive to the date of this Statement.

2. 24-Hour Emergency Service $0.11

Provider certifies availability of 24 hours/day, 365 days/year prescription service_____ Yes_____ No

If yes, identify below the method used by your pharmacy to post notification of this service.

___ Window Sign ___ Prescription Counter Sign

___ Other Note: If "Other" is checked, please attach a complete description of the notification method used by your pharmacy notifying beneficiaries of this service.

24-Hour Emergency Service Telephone Number (___)_____

The 24 Hour Emergency Service Telephone Number must be a local call for beneficiaries serviced by your pharmacy. Failure to provide this number will result in the return of this form.

Note: If a provider discontinues 24-hour emergency service, the provider must notify Unisys, in writing, at PO Box 4804, Trenton, NJ 08650-4804 within 72 hours of this decision, and must immediately cease adding the increment to the basic dispensing fee.

3. Patient Consultation $0.08

Provider agrees to monitor all Medicaid/NJ FamilyCare/PAAD/ADDP/ CF/SGPD patient profiles, in accordance with New Jersey State Board of Pharmacy regulations (N.J.A.C. 13:39-7.14), and those requirements described by the Omnibus Budget Reconciliation Act (OBRA) of 1993. These requirements include, but are not limited to, offers to consult with beneficiaries concerning proper drug administration/storage, and potential drug interactions/conflicts identified by reviews of patient profiles, or as advised by the State's Point of Sale (POS)/Prospective Drug Utilization Review (PDUR) claims processing system. ____ Yes _____No

SECTION II. OWNERSHIP DISCLOSURE STATEMENT

1. _____Pharmacy Name

Chain Pharmacy ___ Yes ___ No

If yes, please indicate the number of pharmacies operating in the State of New Jersey: _____.

2. Does any person in your organization currently own or have an interest in or any relationship with any other corporation, partnership, or other organization providing services under the New Jersey Medicaid, NJ FamilyCare, PAAD, ADDP, CF or SGPD programs? ___ Yes ___ No

If yes, please explain such affiliations on a separate page and attach to the Certification Statement.

3. Indicate the legal status of your organization below.

___ Sole Proprietor ___ Partnership ___ Non-Profit Corporation

___ For-Profit Corporation ___ Government ___ Other (Specify)

List names, professional degrees, home addresses, and percentage of ownership for all partners, directors, officers, and/or stockholders, as applicable:

NAME DEGREE HOME ADDRESS % OWNERSHIP

1. _____
2. _____
3. _____
4. _____
5. _____

I HAVE READ THE PHARMACY PROVIDER CERTIFICATION STATEMENT AND AGREE TO THE TERMS AND CONDITIONS SET FORTH HEREIN. I UNDERSTAND THAT THE MAXIMUM CHARGE TO THE STATE OF NEW JERSEY FOR ALL MEDICAID, NJ FAMILYCARE, PAAD, ADDP, CF AND SGPD PRESCRIPTIONS FOR COVERED DRUGS AND RELATED PHARMACEUTICAL PRODUCTS/DEVICES MAY NOT EXCEED THE PRICING POLICIES OF THE STATE AS DESCRIBED IN N.J.A.C. 10:51-1.7 AND N.J.A.C. 8:83C-1.

Legal Signature of Principal: _____ Date: _____

Print Name:_____

Title: _____

Pharmacy Name: _____

NOTE: ALL STATEMENTS IN THIS CERTIFICATION ARE SUBJECT TO AUDIT AND REVIEW BY THE NEW JERSEY DIVISION OF MEDICAL ASSISTANCE AND HEALTH SERVICES (DMAHS) AND/OR THE NEW JERSEY DEPARTMENT OF HEALTH AND SENIOR SERVICES (DHSS), THEIR CONTRACTORS, OR OTHER STATE AND FEDERAL AGENCIES.

AFFIX
PHARMACY LABEL
HERE

FD-70 (REV. 10/02)

APPENDIX D

FISCAL AGENT BILLING SUPPLEMENT

AGENCY NOTE: The Fiscal Agency Billing Supplement is filed as an incorporated Appendix of this chapter but is not reproduced in the New Jersey Administrative Code. When revisions are made to the fiscal agent billing supplement, replacement pages will be distributed to providers, placed on the website at www.njmmis.com and copies will be filed with the Office of Administrative Law. For a copy of the Fiscal Agent Billing Supplement, write to:

Unisys
PO Box 4801
Trenton, New Jersey 08650-4801

or contact:

Office of Administrative Law
Quakerbridge Plaza, Building 9
PO Box 049
Trenton, New Jersey 08625-0049

APPENDIX E

ELECTRONIC MEDIA CLAIMS (EMC) MANUAL

AGENCY NOTE: The Electronic Media Claims (EMC) Manual is filed as an incorporated Appendix of this chapter, but is not reproduced in the New Jersey Administrative Code. When revisions are made to the EMC Manual, replacement pages will be distributed to providers, placed on the website at www.njmmis.com and copies will be filed with the Office of Administrative Law. For a copy of the EMC Manual, write to:

Unisys
PO Box 4801
Trenton, New Jersey 08650-4801

APPENDIX F
MEDICAID REBATE PROGRAM
MANUFACTURERS' LABELER CODE LIST

Appendix F is a list of drug manufacturers, identified by labeler code, whose drug products are covered by the New Jersey Medicaid and NJ FamilyCare fee-for- service programs. These drug manufacturers have in effect a rebate agreement pursuant to 42 U.S.C. § 1396r-8(a), (b) and (c). This list is updated periodically by the Health Care Financing Administration subsequent to published listing changes in the Federal Register.

AGENCY NOTE: The Appendix F is filed as a part of this chapter but is not reproduced in the New Jersey Administrative Code. When revisions are made to the Appendix F, replacement pages will be distributed to providers, placed on the website at www.njmmis.com and copies will be filed with the Office of Administrative Law. For a copy of the Appendix F, write to:

Unisys
PO Box 4801
Trenton, New Jersey 08650-4801

or contact:

Office of Administrative Law
Quakerbridge Plaza, Building 9
PO Box 049
Trenton, New Jersey 08625-0049

APPENDIX G
STATE OF NEW JERSEY
DEPARTMENT OF HUMAN SERVICES
DIVISION OF MEDICAL ASSISTANCE AND HEALTH SERVICES
NOTIFICATION OF PHARMACEUTICAL SERVICES IN NURSING FACILITIES

_____
(SERVICING PHARMACY)

_____
(PROVIDER NUMBER OF SERVICING PHARMACY)
(IF AVAILABLE)

PROVIDER AGREES:

1. To comply with State regulations, in accordance with N.J.A.C. 10:51, Subchapter 2, when providing pharmaceutical services to:

   _____
   (Nursing Facility)

   Nursing Facility Provider Number: _____

2. In accordance with N.J.A.C. 10:51-2.7(d), the servicing pharmacy shall notify the New Jersey Division of Medical Assistance and Health Services of any change in status regarding the provision of these pharmaceutical services described to avoid improper capitation payments.

3. In accordance with N.J.A.C. 10:51-2.7(d), the pharmacy identified by this agreement shall provide the Division with information requested below:

   (i) A copy of a fully executed agreement between the servicing pharmacy provider and the nursing facility.

   (ii) The effective date of initiating a new or changed pharmaceutical service to:

   _____ is _____
   (Nursing Facility) (Date)

   (iii) Level of Service to be provided: (Select One)

   ___ (01) Twenty-Four (24) Hour Unit Dose Services
   ___ (02) Modified Unit Dose Services (i.e., Bingo, Atromick; 30 day supply)
   ___ (03) Traditional Services (i.e., drug vial dispensing)

___ (04) Twenty-Four (24) Hour Unit Dose Services and ancillary computerized services

___ (05) Modified Unit Dose Services and ancillary computerized services

___ (06) Traditional Services and ancillary computerized services

Note: Ancillary computerized services, if provided, shall include, but not be limited to, continuously updated computerized patient profile records medication sheets, treatment sheets and physician order sheets which must be supplied at least monthly.

The completed agreement must be returned by mail to:

Unisys Corporation
Provider Enrollment Unit
PO Box 4804
Trenton, NJ 08650-4804

PS-I-08(03/94)